Evaluation Report ERC2010-04

Pyroxsulam

(publié aussi en français) **14 May 2010**

This document is published by the Health Canada Pest Management Regulatory Agency. For further information, please contact:

Publications
Pest Management Regulatory Agency
Health Canada
2720 Riverside Drive
A.L. 6604-E2
Ottawa, Ontario
K1A 0K9

Internet: pmra.publications@hc-sc.gc.ca
healthcanada.gc.ca/pmra
Facsimile: 613-736-3758
Information Service:
1-800-267-6315 or 613-736-3799
pmra.infoserv@hc-sc.gc.ca

Canada

HC Pub: 100115

ISBN: 978-1-100-14144-2 (978-1-100-14145-9)
Catalogue number: H113-26/2010-4E (H113-26/2010-4E-PDF)

Table of Contents

Overview

Registration Decision for Pyroxsulam

Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and Regulations, has granted conditional registration for the sale and use of Pyroxsulam Technical Herbicide and Simplicity Herbicide, containing the technical grade active ingredient pyroxsulam, to control broadleaf and grassy weeds in spring wheat and durum wheat using ground or aerial application equipment.

An evaluation of available scientific information found that, under the approved conditions of use, the product has value and does not present an unacceptable risk to human health or the environment.

Although the risks and value have been found acceptable when all risk reduction measures are followed, the applicant must submit additional scientific information as a condition of registration.

This Overview describes the key points of the evaluation, while the Science Evaluation provides detailed technical information on the human health, environmental and value assessments of Pyroxsulam Technical Herbicide and Simplicity Herbicide.

What Does Health Canada Consider When Making a Registration Decision?

The key objective of the *Pest Control Products Act* is to prevent unacceptable risks to people and the environment from the use of pest control products. Health or environmental risk is considered acceptable[1] if there is reasonable certainty that no harm to human health, future generations or the environment will result from use or exposure to the product under its proposed conditions of registration. The Act also requires that products have value[2] when used according to the label directions. Conditions of registration may include special precautionary measures on the product label to further reduce risk.

To reach its decisions, the PMRA applies modern, rigorous risk-assessment methods and policies. These methods consider the unique characteristics of sensitive subpopulations in humans (e.g. children) as well as organisms in the environment (e.g. those most sensitive to environmental contaminants). These methods and policies also consider the nature of the effects observed and the uncertainties when predicting the impact of pesticides. For more information

---

1 "Acceptable risks" as defined by subsection 2(2) of the *Pest Control Products Act*.

2 "Value" as defined by subsection 2(1) of the *Pest Control Products Act*: "the product's actual or potential contribution to pest management, taking into account its conditions or proposed conditions of registration, and includes the product's *(a)* efficacy; *(b)* effect on host organisms in connection with which it is intended to be used; and *(c)* health, safety and environmental benefits and social and economic impact."

on how the PMRA regulates pesticides, the assessment process and risk-reduction programs, please visit the PMRA's website at www.hc-sc.gc.ca/cps-spc/pest/index-eng.php.

What Is Pyroxsulam?

Pyroxsulam is the active ingredient in the end-use product Simplicity Herbicide. Simplicity Herbicide is a postemergence herbicide, i.e., a herbicide applied after the crop has emerged from the ground, which is applied to spring wheat and durum wheat using ground or aerial application equipment to control broadleaf and grassy weeds. Pyroxsulam inhibits the plant enzyme acetolactate synthase (ALS) in target weeds. Complete desiccation of the plant may occur in seven to ten days under ideal growing conditions.

Health Considerations

Can Approved Uses of Pyroxsulam Affect Human Health?

Pyroxsulam is unlikely to affect your health when used according to the label directions.

Exposure to pyroxsulam may occur through diet (food and water), or when handling or applying the product. When assessing health risks, two key factors are considered: the levels where no health effects occur and the levels to which people may be exposed. Toxicology studies in laboratory animals describe potential health effects from varying levels of exposure to a chemical and identify the dose where no effects are observed. The health effects noted in animals occur at doses more than 100-times higher (and often much higher) than levels to which humans are normally exposed when products containing pyroxsulam are used according to label directions.

Both the technical grade active ingredient, Pyroxsulam Technical Herbicide, and the end-use product, Simplicity Herbicide, are considered to be potential skin sensitizers; consequently, the label statement "Potential Skin Sensitizer" is required. The end-use product, Simplicity Herbicide, was considered to be of slight acute toxicity by the inhalation route and moderately irritating to eyes and skin, resulting in the requirement for the label statements "Warning Poison" and "Eye and Skin Irritant".

Pyroxsulam was not genotoxic and did not cause cancer in animals. There were no indications that pyroxsulam caused damage to the developing fetus, the reproductive system, or the nervous system. Health effects in animals given daily doses of pyroxsulam over long periods of time included effects on the liver.

A risk assessment is conducted to ensure that the level of human exposure is well below the lowest dose at which these effects occurred in animal tests. The dose levels used to assess risks are established to protect the most sensitive human population (e.g., children and nursing mothers). Only those uses for which exposure is well below levels that cause no effects in animal testing are considered acceptable for registration.

Residues in Water and Food

Dietary risks from food and water are not of concern

Reference doses define levels to which an individual can be exposed over a single day (acute) or lifetime (chronic) and expect no adverse health effects. Generally, dietary exposure from food and water is acceptable if it is less than 100% of the acute reference dose or chronic reference dose (acceptable daily intake). An acceptable daily intake is an estimate of the level of daily exposure to a pesticide residue that, over a lifetime, is believed to have no significant harmful effects.

Aggregate dietary intake estimates (food plus water) revealed that the general population and infants, the subpopulation which would ingest the most pyroxsulam relative to body weight, are expected to be exposed to less than 1% of the acceptable daily intake. Based on these estimates, the chronic dietary risk from pyroxsulam is not of concern for all population sub-groups. The lifetime cancer risk from the use of pyroxsulam on wheat is considered acceptable.

Animal studies revealed no acute health effects. No endpoint of concern attributable to a single dose was identified. Consequently, a single dose of pyroxsulam is not likely to cause acute health effects in the general population (including infants and children).

The Food and Drugs Act (FDA) prohibits the sale of adulterated food, that is, food containing a pesticide residue that exceeds the established maximum residue limit (MRL). Pesticide MRLs are established for FDA purposes through the evaluation of scientific data under the Pest Control Products Act (PCPA). Food containing a pesticide residue that does not exceed the established MRL does not pose an unacceptable health risk.

Residue trials conducted throughout Canada using pyroxsulam on wheat were acceptable. The MRLs for this active ingredient can be found in the Science Evaluation section of this Evaluation Report.

Risks in Residential and Other Non-Occupational Environments

Estimated risk for non-occupational exposure is not of concern as this is a commercial agricultural product.

Occupational Risks From Handling

Occupational risks are not of concern when Simplicity Herbicide is used according to the label directions, which include protective measures.

A quantitative risk assessment was conducted for individuals handling Simplicity Herbicide. The risk to workers is not of concern when the product is used according to label directions.

Pesticide applicators mixing, loading and applying Simplicity Herbicide can come in direct contact with the product on the skin or through inhalation. Therefore, the label will specify the following.

"At all times: Wear clean clothing with full length sleeves and pants. Wear coveralls over long sleeved shirt and long pants, chemical resistant gloves, socks and chemical resistant footwear during mixing, loading, application, clean up and repair. Wear goggles or face shield during mixing/loading. For closed cab or aerial application, coveralls and gloves are not necessary."

The potential exposure of workers entering treated areas for postapplication activities, such as scouting or irrigation, is acceptable.

Environmental Considerations

What Happens When Pyroxsulam Is Introduced Into the Environment?

Pyroxsulam can pose a risk to terrestrial and aquatic vascular plants, and the formulation Simplicity Herbicide can pose a risk to amphibians; therefore, buffer zones are required during application.

Pyroxsulam enters the environment when used as a herbicide on wheat. It is stable to hydrolysis but can phototransform in shallow, clear, water bodies. Pyroxsulam is non-persistent to slightly persistent in aerobic soil and in water. It is however considered persistent under anaerobic conditions. Pyroxsulam and its transformation products are expected to leach through the soil profile beyond 30 cm in some soils and therefore may be expected to enter groundwater. Based on Canadian field studies, residues of pyroxsulam and its transformation products are not expected to significantly carry over into the next growing season. Based on its low volatility, pyroxsulam residues are not expected in the air.

Pyroxsulam and its major transformation products present a negligible risk to wild mammals, birds, earthworms, bees and other arthropods, aquatic invertebrates, fish, and green algae. However, given that pyroxsulam is a herbicide, it is expected to adversely affect terrestrial plants in adjacent areas. Buffer zones of 2 metres for ground application and 55 to 65 metres for aerial application (depending on application equipment) are required to protect nearby terrestrial plants from the effects of spray drift. Pyroxsulam can potentially affect aquatic vascular plants in adjacent areas, while an aromatic petroleum distillate in the formulation Simplicity Herbicide can potentially affect amphibians in adjacent areas. Therefore, a buffer zone of 1 metre is required to protect aquatic vascular plants and amphibians from the effects of spray drift.

Value Considerations

What Is the Value of Simplicity Herbicide

Simplicity Herbicide, a postemergence herbicide, controls wild oats and broadleaf weeds in spring wheat and durum wheat.

A single application of Simplicity Herbicide provides effective control of a range of broadleaf weeds and wild oats in spring wheat and durum wheat. It is also compatible with integrated weed management practices and with conservation tillage and conventional crop production systems. Because Simplicity Herbicide is applied after weeds have emerged, producers can better assess whether the herbicide is necessary or suitable for particular weed species. Simplicity Herbicide provides an alternative to Group 1 herbicides, which are of concern given the spread of acetyl-CoA carboxylase resistant (ACCase-resistant) wild oats.

Measures to Minimize Risk

Labels of registered pesticide products include specific instructions for use. Directions include risk-reduction measures to protect human and environmental health. These directions must be followed by law.

The key risk-reduction measures being proposed on the label of Simplicity Herbicide to address the potential risks identified in this assessment are as follows.

Key Risk-Reduction Measures

Human Health

Because there is a concern with users coming into direct contact with Simplicity Herbicide on the skin or through inhalation of spray mists, anyone mixing, loading and applying Simplicity Herbicide must wear the PPE that is recommended on the label. Since this product could be applied by aerial application, a statement was added to the label to not use human flaggers. In addition, standard statements to protect against drift during application were added to the label.

Environment

Spray drift of Simplicity Herbicide can pose a risk to terrestrial plants, aquatic vascular plants and amphibians. To mitigate the risk from the effects of spray drift, a buffer zone of 1 metre is required for the protection of sensitive freshwater habitats, and buffer zones of 2 to 65 metres, depending on the type of application equipment, are required to protect sensitive terrestrial habitats. These buffer zones are specified on the product label.

Other environmental concerns associated with pyroxsulam and Simplicity Herbicide were: the leaching potential of pyroxsulam and its transformation products; runoff; and the aromatic petroleum distillate present as a component in the formulation. These concerns were mitigated with label statements on the product label.

What Additional Scientific Information Is Being Requested?

Although the risks and value have been found acceptable when all risk-reduction measures are followed, the applicant must submit additional scientific information as a condition of registration. More details are presented in the Science Evaluation of this Evaluation Report or in the Section 12 Notice associated with these conditional registrations.

Environment

1. Provide the octanol-water partition coefficient (log K_{ow}) for the transformation product pyroxsulam sulfonamide to determine its potential bioaccumulation under TSMP. The study should be conducted under GLP.

2. Provide a new toxicity study for pyroxsulam on the freshwater diatom, *Navicula pelliculosa*. The study must conform to standard international guidelines (e.g. USEPA, OECD) and be conducted under GLP.

Chemistry

1. Analytical data from at least five batches of Pyroxsulam Technical Herbicide representing full-scale production.

Other Information

As these conditional registrations relate to a decision on which the public must be consulted,[3] the PMRA will publish a consultation document when there is a proposed decision on applications to convert the conditional registrations to full registrations or on applications to renew the conditional registrations, whichever occurs first.

The test data cited in this Evaluation Report (i.e. the test data relevant in supporting the registration decision) will be made available for public inspection when the decision is made to convert the conditional registrations to full registrations or to renew the conditional registrations (following public consultation). If more information is required, please contact the PMRA's Pest Management Information Service by phone (1-800-267-6315) or by e-mail (pmra.infoserv@hc-sc.gc.ca).

---

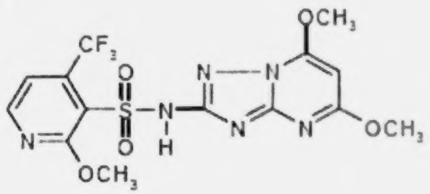
[3] As per subsection 28(1) of the *Pest Control Products Act*.

Science Evaluation

Pyroxsulam

1.0 The Active Ingredient, Its Properties and Uses

1.1 Identity of the Active Ingredient

Active substance	Pyroxsulam
Function	Herbicide
Chemical name	
1. International Union of Pure and Applied Chemistry (IUPAC)	N-(5,7-dimethoxy[1,2,4]triazolo[1,5-a]pyrimidin-2-yl)-2-methoxy-4-(trifluoromethyl)pyridine-3-sulfonamide
2. Chemical Abstracts Service (CAS)	N-(5,7-dimethoxy[1,2,4]triazolo[1,5-a]pyrimidin-2-yl)-2-methoxy-4-(trifluoromethyl)-3-pyridinesulfonamide
CAS number	422556-08-9
Molecular formula	$C_{14}H_{13}F_3N_6O_5S$
Molecular weight	434.4
Structural formula	
Purity of the active ingredient	99.0% (96-100%)

1.2 Physical and Chemical Properties of the Active Substances and End-use Product Technical Product—Pyroxsulam Technical Herbicide

Property	Result
Colour and physical state	Off-white
Odour	Spicy odour
Melting point	208.3°C
Boiling point or range	Not applicable
Density	1.618 g/mL
Vapour pressure at 20°C	$< 1 \times 10^{-7}$ Pa
Henry's law constant at 20°C	1.34×10^{-13} atm m^3/mol at 20°C
Ultraviolet (UV)-visible spectrum	No UV absorption above 350 nm (λmax=297nm)
Solubility in water at 20°C (g/L)	Purified water 0.0626 pH 4 buffer 0.0164 pH 7 buffer 3.20 pH 9 buffer 13.7
Solubility in organic solvents at 20°C (g/L)	<u>**Solvent**</u> <u>**Solubility**</u> methanol 1.01 Acetone 2.79 N-Octanol 0.0730 Ethyl acetate 2.17 1,2-Dichloromethane 3.94 Xylene 0.0352 Heptane <0.001

Property	Result
n-Octanol-water partition coefficient (K_{ow})	<u>pH</u> <u>log K_{ow}</u> 4 1.08 7 -1.01 9 -1.60
Dissociation constant (pK_a)	4.67
Stability (temperature, metal)	Does not contain any oxidizing or reducing agents.

End-use Product— Simplicity Herbicide

Property	Result
Colour	Brown opaque
Odour	Mild
Physical state	Liquid
Formulation type	Suspension
Guarantee	30 g/L (28.5-31.5 g/L)
Container material and description	Bulk High Density Polyethylene (HDPE), Polyethylene Terephthalate (PET) plastic jugs.
Density	1.0421 g/mL
pH of 1% dispersion in water	6.21 (1 % w/v dilution in water)
Oxidizing or reducing action	No significant increase of temperature was observed after the addition of water, zinc metal, monoammonium phosphate, or potassium permanganate.
Storage stability	Stable at ambient temperature in its commercial container.
Explodability	Not explosive

1.3 Directions for Use

Simplicity Herbicide is a selective herbicide for use as a postemergence treatment on spring wheat and durum wheat for the control of specific broadleaf and grass weeds. The product can be applied at a rate of 15 g a.i./ha. Simplicity Herbicide must be applied with the adjuvant Assist Oil Concentrate. The product is applied as a broadcast treatment with either groundboom or aerial equipment. Simplicity Herbicide may be applied once per growing season with a maximum application rate of 15 g a.i./ha.

Weed Control and Suppression Claims for Simplicity Herbicide*

Herbicide Rate	Weeds Controlled	Weeds Suppressed
15 g a.i./ha or 500 mL product/ha	wild oats, common chickweed, cleavers, volunteer canola, hempnettle, smartweed (lady's-thumb), redroot pigweed	green foxtail, wild buckwheat

* Simplicity Herbicide must be applied with Assist Oil Concentrate at a rate of 0.8% v/v.

Simplicity Herbicide may be tankmixed with one of the following six tankmix partners to broaden the spectrum of broadleaf weed control: Frontline XL Herbicide, Frontline Herbicide Tank-Mix, Spectrum Herbicide Tank-Mix, MCPA LV500, Buctril M, or Refine Extra.

1.4 Mode of Action

Pyroxsulam is classified as Group 2 Herbicide (refer to Regulatory Directive DIR99-06, *Voluntary Pesticide Resistance-Management Labelling Based on Target Site/Mode of Action*, for details). The primary mode of action of pyroxsulam is as an inhibitor of the plant enzyme acetolactate synthase (ALS) in target weeds. ALS is a key enzyme in the synthesis of branched-chain amino acids. The inhibition of the ALS enzyme results in a number of distinctive whole plant symptoms. Growth in sensitive plant species is retarded within hours of application although visible effects may not be observed for several days. Symptoms appear first in the upper meristematic regions of the plant as chlorosis and necrosis. The upper new leaves often take on a wilted appearance. The effect then spreads to the remaining parts of the plant. Reddening of the midrib and vein is observed in some species. Complete desiccation of the plant may occur in seven to ten days under ideal growing conditions. Pyroxsulam is readily absorbed by plant foliage and roots; pyroxsulam is mobile in both the xylem and the phloem and accumulates in the primary and auxiliary meristems of the plant.

2.0 Methods of Analysis

2.1 Methods for Analysis of the Technical Grade of Active Ingredient

The methods provided for the analysis of the active ingredient and the impurities in Pyroxsulam Technical Herbicide have been validated and assessed to be acceptable for the determinations.

2.2 Method for Formulation Analysis

The method provided for the analysis of the active ingredient in the formulation has been validated and assessed to be acceptable for use as an enforcement analytical method.

2.3 Methods for Residue Analysis

High-performance liquid chromatography methods with tandem mass spectrometry (HPLC-MS/MS) were developed and proposed for data generation and enforcement purposes. These methods fulfilled the requirements with regards to selectivity, accuracy and precision at the respective method limit of quantitation. Acceptable recoveries (70–120%) were obtained in plant and animal matrices and environmental media. Methods for residue analysis are summarized in Appendix I, Table 1.

A liquid chromatography method with tandem mass spectrometry was developed and proposed for data generation and enforcement purposes for pyroxsulam in wheat. This method fulfilled the requirements with regards to specificity, accuracy and precision at the respective method limit of quantitation. Acceptable recoveries (69-108%) were obtained in a variety of plant matrices that included wheat. Adequate extraction efficiencies were demonstrated in samples of wheat plants harvested 7 days after treatment with pyroxsulam radiolabelled in the pyridine ring that were analyzed using the proposed enforcement method. Pyroxsulam was analyzed according to the Food and Drug Administration's (FDA) Multiresidue Method Testing guidelines in Pesticide Analytical Methods (PAM) Volume I, Appendix II. The multiresidue methods tested (Protocols A, C, and G) are not suitable for analysis of pyroxsulam.

3.0 Impact on Human and Animal Health

3.1 Toxicology Summary

The PMRA conducted a detailed review of the toxicological database for pyroxsulam. The toxicological database is complete, consisting of the full array of laboratory animal (in vivo) and cell culture (in vitro) toxicity studies currently required for health hazard assessment purposes. The studies were carried out in accordance with currently accepted international testing protocols and good laboratory practices. The scientific quality of the data is high and the database is considered adequate to characterize the toxicity of this pest control product.

The toxicokinetics of pyroxsulam were investigated in rats and mice. Pyroxsulam was rapidly absorbed following oral administration with maximum plasma concentrations occurring at 30 minutes following administration of low doses (10 mg/kg bw) in rats and mice and at 1-2 hours following administration of mid (100 mg/kg bw) and high (1000 mg/kg bw) doses in mice. Elimination of pyroxsulam was rapid and nearly complete within 24 hours after dosing. Urinary excretion was the predominant route of elimination following administration of low doses, whereas fecal excretion became more significant following administration of higher doses indicating saturation of absorption. Pyroxsulam was largely unmetabolized; a minor amount of

parent compound underwent simple metabolism to a single metabolite, 2-demethyl- pyroxsulam, via O-dealkylation.

Pyroxsulam and its end-use product, Simplicity Herbicide, were found to be of low acute toxicity via the oral and dermal routes. Pyroxsulam was found to be of low toxicity via the inhalation route, while Simplicity Herbicide was considered to be of slight toxicity via this route. Pyroxsulam was non-irritating to the skin and minimally irritating to the eyes. Simplicity Herbicide was determined to be moderately irritating to the skin and eyes. Both pyroxsulam and Simplicity Herbicide were found to be potential dermal sensitizers.

No treatment-related effects were noted in a 14-day range-finding dermal toxicity study; however, this study was considered supplemental as only three animals/sex were used and limited evaluations were conducted. A request was made by the applicant to waive the requirement for a 28-day dermal toxicity study based on the lack of obvious signs of toxicity in the 14-day range-finding study.

In the short- and long-term oral toxicity studies in rats, no toxicologically significant effects were noted when animals were dosed up to the limit dose of 1000 mg/kg bw/day (or higher). In the mouse, effects indicative of liver toxicity were noted in males at the limit dose only following long-term exposure (18 months). Effects included increased liver weight as well as increased incidences of liver masses and foci of altered hepatocytes. Foci of altered hepatocytes were characterized by the cytoplasmic staining of the majority of the cells in the focus. Treatment-related increases in the number of clear (vacuolated) cell foci and lesser increases in the number of mixed or eosinophilic cell foci were observed. As no toxicologically significant effects were noted in mice following subchronic exposure to pyroxsulam, it is evident that mice are susceptible to increased toxicity following increased duration of exposure.

In the oral toxicity studies in the dog, no toxicologically significant effects were noted in males in the 90-day study (when fed diets providing doses up to 884 mg/kg bw/day) or in either sex in the 1-year study (when fed diets providing doses up to 620 and 589 mg/kg bw/day in males and females, respectively). In females, minimal liver toxicity in the form of increased weight and very slight hepatoceullular hypertrophy, as well as reduced food efficiency were noted at a dose exceeding the limit dose (1142 mg/kg bw/day) following 90 days of exposure.

Pyroxsulam did not exhibit oncogenic or genotoxic potential. There was no evidence of neurotoxicity in the toxicological database, which included a one-year neurotoxicity study in rats.

No treatment-related effects were observed in the reproductive or developmental toxicity studies in the rat. In the rabbit developmental toxicity study, minimal decreases in body weight gain and food consumption were noted in pregnant animals during the dosing period at 300 mg/kg bw/day. However, it was determined that the doses used in the rabbit developmental toxicity study were not high enough based on the range-finding study that indicated that doses as high as 600 or possibly 1000 mg/kg bw/day could have been tolerated by the maternal animals in the main study. At 600 mg/kg bw/day in the range-finding study, minimal body weight decrements

were noted in maternal animals. No cesarian section or fetal effects were noted in the range-finding study, although the fetal assessments were limited to an evaluation of external morphology; consequently, no skeletal or visceral effects, if present, would have been observed. Dams dosed with 1000 mg/kg bw/day of pyroxsulam in the range-finding study were sacrificed early due to body weight losses and reduced food intake in only two (out of six) dams; no cesarian section or fetal assessments were conducted at 1000 mg/kg bw/day due to the early sacrifice of maternal animals. The results from the range-finding study indicate that a dose of 600 mg/kg bw/day produced only minimal toxicity in dams and no overt signs of developmental toxicity (i.e., no external deviations or malformations) in fetuses.

3.1.1 Pest Control Products Act Hazard Characterization

For assessing risks from potential residues in food or from products used in or around homes or schools, the *Pest Control Products Act* requires the application of an additional 10-fold factor to threshold effects. This factor should take into account potential prenatal and postnatal toxicity and completeness of the data with respect to the exposure of and toxicity to infants and children. A different factor may be determined to be appropriate on the basis of reliable scientific data.

With respect to the completeness of the toxicity database for the assessment of risk to infants and children, the database contains the full complement of required studies including developmental toxicity studies in rats and rabbits and a reproductive toxicity study in rats. As noted above, it was determined that the doses used in the rabbit developmental toxicity study were inadequate. A developmental neurotoxicity study was not required based on the toxicological profile of Pyroxsulam Technical Herbicide (i.e., there were neither signs of neurotoxicity in the toxicological nor evidence of increased susceptibility of the young).

With respect to identified concerns relevant to the assessment of risk to infants and children, there was no indication of increased susceptibility in the offspring compared to parental animals in the reproduction study, nor was there any indication of increased susceptibility of rat or rabbit fetuses to in utero exposure to Pyroxsulam Technical Herbicide in the prenatal developmental toxicity studies.

Despite the inadequacy of the doses used in the rabbit developmental toxicity study, the 10-fold factor required under the *Pest Control Products Act* factor can be reduced to 1 because the level of concern for developmental toxicity in the rabbit is low given the generally low systemic toxicity indicated by the toxicology database for Pyroxsulam Technical Herbicide and the lack of developmental and offspring toxicity in the rat. In addition, adequate coverage to the NOAEL in the rabbit developmental toxicity study is provided by the selection of endpoints for use in the dietary and occupational/bystander exposure risk assessments.

3.2 Determination of Acceptable Daily Intake

The recommended acceptable daily intake (ADI) is 1.0 mg/kg bw/day, calculated using the NOAEL in males of 100 mg/kg bw/day from the 18-month dietary study in the mouse. Treatment-related effects at the lowest observed adverse effect level (LOAEL) of 932 mg/kg bw/day in males included increased liver weight, increased incidence of masses or nodules of the liver, and increased incidence of foci of altered hepatocytes. This study is of appropriate route and duration. The standard uncertainty factor (UF) of 100 has been applied to account for interspecies extrapolation and intraspecies variability.

The ADI is calculated according to the following formula:

$$\text{ADI} = \frac{\text{NOAEL}}{\text{UF}} = \frac{100 \text{ mg/kg bw/day}}{100} = 1.0 \text{ mg/kg bw/day}$$

The ADI of 1.0 mg/kg bw/day provides an adequate margin (300) to the highest dose tested in the rabbit developmental toxicity study (300 mg/kg bw/day), in which the dosing was considered to be inadequate due to the absence of toxicologically significant effects in the maternal animals.

3.3 Acute Reference Dose (ARfD)

An acute reference dose was not established since no hazard following an acute exposure was identified in the toxicology database.

3.4 Occupational and Residential Risk Assessment

3.4.1 Toxicological Endpoint Selection: Occupational and Bystander Risk Assessment

Occupational and bystander exposure to pyroxsulam is characterized as short- to intermediate-term in duration and is likely to occur through the dermal and inhalation routes.

For short- and intermediate-term dermal and inhalation exposure, the NOAEL in males of 100 mg/kg bw/day from the 18-month dietary study in the mouse was selected. Treatment-related effects at the LOAEL of 932 mg/kg bw/day in males included increased liver weight, increased incidence of masses or nodules of the liver, and increased incidence of foci of altered hepatocytes. The target margin of exposure (MOE) of 100 is considered appropriate to account for interspecies extrapolation and intraspecies variability. This endpoint and target MOE provide an adequate margin (300) to the highest dose tested in the rabbit developmental toxicity study (300 mg/kg bw/day), in which the dosing was considered to be inadequate due to the absence of toxicologically significant effects in the maternal animals.

The 14-day range-finding dermal toxicity study was not considered to be appropriate for use in the risk assessment because of its many limitations, and the absence of effects in this study does not provide sufficient evidence to conclude that a dermal risk assessment is not required. However, taking into consideration the lack of overt signs of toxicity in the 14-day study up to the limit dose of 1000 mg/kg bw/day and the overall low systemic toxicity via the oral route demonstrated in the toxicological database, defaulting to an oral endpoint is considered to be protective of any potential effects that would be observed following short- to intermediate-term dermal exposure to pyroxsulam. Therefore, a 28-day dermal toxicity study is not being required at this time, nor are additional factors deemed necessary for the lack of such a study.

A repeated-exposure inhalation study conducted with pyroxsulam was not provided, but was not required based on its low acute toxicity via the inhalation route, its low volatility (vapour pressure < 1×10^{-7} kPa), and its overall low systemic toxicity as demonstrated in the oral toxicity studies. Therefore, the selection of an endpoint from an oral toxicity study is considered to be appropriate for the assessment of risk via the inhalation route of exposure.

The NOAEL established for females in the 90-day oral toxicity study in the dog (98.6 mg/kg bw/day) is slightly lower numerically than the NOAEL of 100 mg/kg bw/day from the 18-month dietary study in the mouse selected for the occupational and bystander risk assessment; however, the two NOAEL values are considered to be virtually equivalent. Although a 90-day study would be considered to be a more appropriate duration of exposure for extrapolation to short- to intermediate-term exposures than an 18-month study, the NOAEL in the 18-month study was considered more appropriate for use in this risk assessment because the LOAEL in the 90-day oral toxicity study in the dog (1142 mg/kg bw/day) is in excess of the limit dose and the effects noted at this dose were considered marginal and were not repeated in the 1-year dog study.

Results of the acute and chronic tests conducted on laboratory animals with pyroxsulam and its associated end-use product Simplicity Herbicide, as well as the toxicological endpoints selected for the human health risk assessment, are summarized in Tables 2, 3 and 4 of Appendix I.

3.4.1.1 Dermal Absorption

No information was submitted by the applicant to address dermal absorption. In the absence of a chemical specific *in vivo* dermal absorption study in rats, standard defaults regarding dermal absorption will be used in the assessment (i.e. 100% dermal absorption).

3.4.2 Occupational Exposure and Risk

3.4.2.1 Mixer/Loader/Applicator Exposure and Risk

Individuals have potential for exposure to Simplicity Herbicide during mixing, loading and application. Exposure is expected to be short-term to intermediate-term in duration. This product is intended for application with groundboom equipment, or by air using fixed-wing or rotary aircraft equipment. For groundboom application, mixing/loading may be accomplished with

either an open pour system or a liquid closed mixing/loading system and the same person may be involved in mixing/loading, application and clean-up activities. For aerial application, mixing/loading can be accomplished with a liquid closed mixing/loading system. The product label advises that the pilot must not mix chemicals to be loaded onto the aircraft, although loading of premixed chemicals with a closed system is permitted. Application equipment is typically cleaned when moving from one crop to another.

Exposure estimates for mixers, loaders, applicators (M/L/A) are based on data from the Pesticide Handlers Exposure Database (PHED) version 1.1. The PHED is a compilation of generic mixer/loader and applicator passive dosimetry data with associated software which facilitates the generation of scenario-specific exposure estimates. To estimate exposure for each use scenario, appropriate subsets of A and B grade data were created from the database files of PHED for liquid open mixing and loading and closed mixing and loading, groundboom application open cab, and aerial (fixed wing & rotary- wing)/ liquid application. All data were normalized for kg of active ingredient handled. Exposure estimates are presented on the basis of the best-fit measure of central tendency, i.e., summing the measure of central tendency for each body part which is most appropriate to the distribution of data for that body part. The confidence level is high.

The estimated worker exposure was based on a worker's body weight of 70 kg and dermal absorption of 100% for males and females. Exposure estimates are based on anyone mixing or loading Simplicity Herbicide, or engaging in cleanup or repair activities, wearing a single layer of protective clothing consisting of long-sleeved shirt and long pants, chemical-resistant gloves, shoes and socks, and goggles or a face shield, and that anyone applying the product wearing a long-sleeved shirt and long pants.

Dermal and inhalation exposure estimates for individuals who mix, load and apply Simplicity Herbicide were combined and compared to the NOAEL of 100 mg/kg bw/day from an 18-month dietary study in mice. All MOEs exceed the target of 100 and are considered acceptable.

Table 3.4.2.1 Mixer/Loader/Applicator Exposure Estimates for Simplicity Herbicide on wheat

Scenario		PHED Unit Exposure (µg a.i./kg a.i. handled)[a+b]		Exposure Pattern	Daily Dose (µg a.i./kg bw/day)[c]			Combined MOE[d]
		Dermal	Inhalation		Dermal	Inhalation	Total	
Ground boom	Farmer	84.12	2.56	Application to 150 ha at 0.015 kg a.i./ha (2.25 kg a.i./day)	2.70	0.08	2.78	35900
	Custom	84.12	2.56	Application to 300 ha at 0.015 kg a.i./ha (4.5 kg a.i./day)	5.41	0.16	5.57	17900
Aerial	Custom M/L	51.14	1.6	Application to 490 ha at 0.015 kg a.i./ha (7.35 kg a.i./day)	5.37	0.16	5.53	18100
	Custom A	9.66	0.07	Application to 490 ha at 0.015 kg a.i./ha (7.35 kg a.i./day)	1.01	0.01	1.02	98000

a Mixer/loader: single layer, gloves for liquid open cab

b Applicator: single layer of clothing, no gloves for groundboom open cab and for aerial
Unit exposure = µg a.i./kg a.i. handled × 100% dermal absorption (dermal only)

c Daily Dose µg a.i./kg a.i. handled × application rate × area treated / 70 kg body weight

d Combined MOE = oral NOAEL of 100 mg a.i./kg bw/day/Total Daily Dose; target margin of exposure of 100.

3.4.2.2 Exposure and Risk Assessment for Workers Entering Treated Area

There is potential for exposure to workers entering treated wheat fields to perform scouting activities and mechanical harvesting, swathing and irrigation. Of these, scouting has the highest potential for exposure.

The duration of exposure is considered to be short-term (30 days or less per year), and the primary route of exposure for workers re-entering treated areas would be through dermal contact with residues on the leaves. Inhalation exposure is expected to be negligible as the vapour pressure of Simplicity Herbicide is less than 1.0×10^{-7} k Pa, making it effectively non-volatile. Dermal exposure to workers entering treated areas is estimated by coupling dislodgeable foliar residue values with activity-specific transfer coefficients. Activity transfer coefficients are based on data from the Agricultural Re-entry Task Force data, of which Dow Agrosciences is a member. Chemical-specific dislodgeable foliar residue data were not submitted. As such, a default dislodgeable foliar residue value of 20% of the application rate was used in the exposure assessment.

For the risk estimates, exposure was compared with the NOAEL of 100 mg/kg/day from an 18-month dietary study in mice. A dermal absorption value of 100% was incorporated into the estimate of systemic exposure.

All margins of exposure are above the target MOE of 100 and are considered acceptable (Table 3.4.2.2).

Table 3.4.2.2 Postapplication Margin of Exposure on Corn

Activity	Exposure (mg a.i./kg bw/day)[a]	Margin of Exposure[b]
Scouting	0.00514	19444

a Estimated as 20% application rate(mg cm^2) × transfer coefficient of 1500 cm^2/hour × 8 hour/day worked × 100% dermal absorption / 70 kg body weight

b NOAEL of 100 mg a.i./kg bw/day; target MOE of 100.

3.4.3 Residential Exposure and Risk Assessment

3.4.3.1 Handler Exposure and Risk

There are no domestic class products; therefore, a residential handler assessment was not required.

3.4.3.2 Postapplication Exposure and Risk

There are no domestic class product or residential uses of commercial products; therefore, a residential post-application assessment was not required.

3.4.3.3 Bystander Exposure and Risk

Bystander exposure to Simplicity Herbicide is considered to be negligible since the potential for drift is expected to be minimal. Application is limited to agricultural crops only when there is low risk of drift to areas of human habitation or activity such as houses, cottages, schools and recreational areas, taking into consideration wind speed, wind direction, temperature inversion, application equipment and sprayer settings.

3.5 Food Residues Exposure Assessment

3.5.1 Residues in Plant and Animal Foodstuffs

The residue definition for risk assessment and enforcement in wheat products and animal commodities is pyroxsulam. The data gathering/enforcement analytical methodology, Method GRM 04.17, is valid for the quantification of pyroxsulam residues in wheat grain, straw, and forage. An enforcement method for animal matrices was not submitted and is not required at this time, as measurable residues are not expected in livestock commodities. The residues of pyroxsulam are stable when stored in a freezer at -20°C for 6 months in a variety of plant matrices including wheat. Residues in processed wheat fractions are not expected. This is based on the results of the crop field trials and metabolism study for wheat where pyroxsulam residues were <0.01 ppm and the TRRs were <0.002 ppm in wheat grain when treated, respectively, at

1X and 2.5X the proposed label rate. Supervised residue trials conducted in Canada using end-use products containing pyroxsulam at the proposed rate for wheat are sufficient to support the proposed maximum residue limit.

3.5.2 Dietary Risk Assessment

Acute and chronic dietary risk assessments were conducted using the Dietary Exposure Evaluation Model (DEEM–FCID™, Version 2.0), which uses updated food consumption data from the United States Department of Agriculture's Continuing Surveys of Food Intakes by Individuals, 1994–1996 and 1998.

3.5.2.1 Chronic Dietary Exposure Results and Characterization

The following assumptions were made in the chronic analysis: residues of pyroxsulam in/on wheat were based on limit of quantitation values for wheat commodities and zero values for all animal commodities. The basic chronic dietary exposure from all supported pyroxsulam food uses (alone) for the total population, including infants and children, and all representative population subgroups are less than 1% of the acceptable daily intake (ADI). Aggregate exposure from food and water is considered acceptable. The PMRA estimates that chronic dietary exposure to pyroxsulam from food and water is less than 1% (0.000510 mg/kg bw/day) of the ADI for the total population. The highest exposure and risk estimate is for children (3-5 years) is less than 1% (0.000727 mg/kg bw/day) of the ADI.

3.5.2.2 Acute Dietary Exposure Results and Characterization

No appropriate endpoint attributable to a single dose for the general population (including children and infants) was identified. Therefore, no acute dietary exposure assessment was conducted.

3.5.3 Aggregate Exposure and Risk

The aggregate risk for pyroxsulam consists of exposure from food and drinking water sources only; there are no residential uses.

3.5.4 Maximum Residue Limits

Table 3.5.4 Proposed Maximum Residue Limits

MRLs (ppm)	Food
0.01	Wheat, grain

For additional information on Maximum Residue Limits (MRL) in terms of the international situation and trade implications, refer to Appendix II.

The nature of the residues in animal and plant matrices, analytical methodology, field trial data, and the chronic dietary risk estimates are summarized in Tables 1, 5 and 6 in Appendix I .

4.0 Impact on the Environment

4.1 Fate and Behaviour in the Environment

Pyroxsulam enters the soil in its use as a herbicide on wheat. Under field conditions relevant to Canada, pyroxsulam is non-persistent to moderately persistent, with half-lives ranging from 5 to 72 days. Identified major transformation products in soil include 5-OH-pyroxsulam, 7-OH-pyroxsulam, 6-Cl-7-OH-pyroxsulam, pyroxsulam sulfonamide and carbon dioxide. Minor transformation products in soil include pyroxsulam pyridine sulfonic acid and pyroxsulam cyanosulfonamide. 7-OH-Pyroxsulam is non-persistent to moderately persistent, with a field half-life of 3 to 97 days. 6-Cl-7-OH-pyroxsulam is moderately persistent, with a half-life of 84 days. A field half-life could not be calculated for 5-OH-pyroxsulam. The route of dissipation of pyroxsulam is primarily through transformation by soil organisms; in addition, binding to soil occurs. Field data indicate that pyroxsulam and transformation product 6-Cl-7-OH-pyroxsulam can leach through the soil profile down to a depth of 60 cm and therefore, may be expected to enter groundwater. Transformation product 7-OH-pyroxsulam was detected down to a depth of 30 cm, while 5-OH-pyroxsulam was detected in the top 15 cm layer of soil. A leaching assessment based on results of laboratory studies of biotransformation and mobility, as wells as field dissipation studies, indicate that pyroxsulam and the transformation products of pyroxsulam have the potential to leach to groundwater.

Pyroxsulam could reach water systems by spray drift or runoff. It is very soluble in water, and the solubility increases with pH. Pyroxsulam is stable to hydrolysis. Phototransformation can be an important route of dissipation of pyroxsulam in the photic zone of aquatic systems (predicted environmental half-life of 4.5 days at 40°N). Pyroxsulam is non-persistent to slightly persistent in aerobic water-sediment systems, with half-lives ranging from 12 to 24 days. Identified major transformation products of pyroxsulam in aquatic systems are 7-OH-pyroxsulam, pyroxsulam-ATSA, 5,7-di-OH-pyroxsulam, 742-sulfinic acid and 742-ADTP. Pyroxsulam pyridine sulfonic acid is the only minor transformation product. The major transformation product 7-OH-pyroxsulam is slightly persistent in aerobic water-sediment systems, with a half-life ranging from 16 to 42 days. Another major transformation product, pyroxsulam-ATSA, is slightly persistent to moderately persistent in aerobic aquatic systems, with a half-life ranging from 22 to 71 days. The majority of residues attributed to pyroxsulam and its major transformation products were detected in the water phase. A large portion of the residues were associated with non-extractable residues in the sediment. Due to lack of adequate data, pyroxsulam is considered stable in anaerobic water-sediment systems.

The low vapour pressure and Henry's law constant indicate that pyroxsulam is non-volatile in the environment. Therefore pyroxsulam residues are not expected in the atmosphere, and long-range transport is not expected.

Data on the fate and behaviour of pyroxsulam and its major transformation products are summarized in Tables 7 and 8 of Appendix I. The transformation pathways for pyroxsulam in aerobic soil and water-sediment systems are summarized in Figures 1 and 2, respectively, of Appendix I.

4.2 Effects on Non-Target Species

The environmental risk assessment integrates the environmental exposure and ecotoxicology information to estimate the potential for adverse effects on non-target species. This integration is achieved by comparing exposure concentrations with effects concentrations. Estimated environmental exposure concentrations (EECs) are concentrations of pesticide in various environmental media, such as food, water, soil and air. The EECs are estimated using standard models which take into consideration the application rate(s), chemical properties and environmental fate properties, including the dissipation of the pesticide between applications. Ecotoxicology information includes acute and chronic toxicity data for various organisms or groups of organisms from both terrestrial and aquatic habitats including invertebrates, vertebrates, and plants. Toxicity endpoints used in risk assessments may be adjusted to account for potential differences in species sensitivity as well as varying protection goals (i.e. protection at the community, population, or individual level).

Initially, a screening level risk assessment is performed to identify pesticides and/or specific uses that do not pose a risk to non-target organisms, and to identify those groups of organisms for which there may be a potential risk. The screening level risk assessment uses simple methods, conservative exposure scenarios (e.g. direct application at a maximum cumulative application rate) and sensitive toxicity endpoints. A risk quotient (RQ) is calculated by dividing the exposure estimate by an appropriate toxicity value (RQ = exposure/toxicity), and the risk quotient is then compared to the level of concern (LOC = 1). If the screening level risk quotient is below the level of concern, the risk is considered negligible and no further risk characterization is necessary. If the screening level risk quotient is equal to or greater than the level of concern, then a refined risk assessment is performed to further characterize the risk. A refined assessment takes into consideration more realistic exposure scenarios (such as drift to non-target habitats) and might consider different toxicity endpoints. Refinements may include further characterization of risk based on exposure modelling, monitoring data, results from field or mesocosm studies, and probabilistic risk assessment methods. Refinements to the risk assessment may continue until the risk is adequately characterized or no further refinements are possible.

The toxicity of pyroxsulam and its transformation products 5-OH-pyroxsulam, 6-Cl-7-OH-pyroxsulam, 5,7-di-OH-pyroxsulam, 7-OH-pyroxsulam, 742-ADTP, pyroxsulam-ATSA and 742-sulfinic acid is summarized in Table 9, Appendix 1.

4.2.1 Effects on Terrestrial Organisms

Risk of pyroxsulam to terrestrial organisms was based upon evaluation of toxicity data for three mammal and two bird species, representing vertebrates; one bee species and one earthworm species representing invertebrates; and ten crop species representing plants. Risk of the transformation products 5-OH-pyroxsulam, 6-Cl-7-OH-pyroxsulam and 7-OH-pyroxsulam was based upon evaluation of toxicity data for one earthworm species representing invertebrates. See Table 9, Appendix I for a summary of the toxicity data reviewed.

For terrestrial vertebrates, pyroxsulam did not cause mortality or clinical signs of toxicity in acute (gavage) limit tests. In an acute (gavage) toxicity test conducted with the end-use product Simplicity Herbicide, mortality and clinical signs of toxicity were observed in rats dosed with 5000 mg/kg bw. No effects of pyroxsulam were observed following short-term or long-term dietary studies in birds and mammals. The risk to wild mammals and birds following acute, short-term or long-term exposure to pyroxsulam at the maximum application rate is below the level of concern; all risk quotients are less than one. (Table 10, Appendix I).

For terrestrial invertebrates, pyroxsulam was not toxic to bees or earthworms in acute dose-response studies, with LC_{50} values exceeding the highest concentration (limit) tested. However, observable sublethal effects (weight loss) were observed in earthworms at the highest pyroxsulam concentration tested. Transformation products 5-OH-pyroxsulam and 6-Cl-7-OH-pyroxsulam were not toxic to earthworms in acute dose-response studies. Observable sublethal effects (weight loss) were observed in the acute earthworm study with transformation product 7-OH-pyroxsulam at all concentrations tested. The number of juveniles produced was reduced at the highest concentration tested in the short-term study with 6-Cl-7-OH-pyroxsulam. The risk to terrestrial invertebrates following acute and short-term exposure to pyroxsulam and transformation products 5-OH-pyroxsulam, 7-OH-pyroxsulam and 6-Cl-7-OH-pyroxsulam at the maximum rate of application is below the level of concern; all risk quotients are less than one (Table 10, Appendix I).

For terrestrial plants, seedling emergence and vegetative vigour were examined. Ten species of plants were exposed to the end-use product Simplicity Herbicide. The end-use product had significant phytotoxic effects (i.e., greater than 25% reduction in health of the plant population) for both seedling emergence and vegetative vigour for all species tested. Vegetative vigour was more sensitive than seedling emergence, with plant shoot height being the most sensitive endpoint. The most sensitive ER_{25} was 0.185 g a.i./ha. Risk quotients calculated under conservative scenarios exceeded the level of concern of one for all four monocotyledonous and six dicotyledonous species tested (Table 10, Appendix I).

A refined assessment considered that the most likely scenario of exposure to non-target plants is through drift. Under this scenario, exposure to off-field (non-target) plants was characterized using empirical spray drift curves to more accurately determine the amount of drift reaching plants 1 metre downwind from the edge of the application swath. Using a standard field sprayer with a boom height of 60 cm above the crop (ground application), as well as an ASAE spray quality of coarse (i.e., a volume median diameter [VMD] of 350 - 450 µm) for this herbicide

application, only 3% of the on-target rate is expected to drift 1 m downwind from the edge of the application site. For aerial application to agricultural crops, 17% of the on-target rate is expected to drift 1 metre downwind from the edge of the application site. The revised expected environmental concentrations and resulting risk quotients from drift (see Table 11, Appendix I) still indicate a risk to off-site non-target plants 1 metre downwind from the edge of the field. The end-use product, Simplicity Herbicide, will therefore require buffer zones to reduce the risk of adverse effects in non-target plants (see Overview section "Measures to Minimize Risk", for full buffer zone requirements).

The end-use product, Simplicity Herbicide, contains an aromatic petroleum distillate. The risk of the aromatic petroleum distillate formulant to terrestrial organisms was determined for the use pattern on wheat, and was based upon toxicity data for one bird species (Table 12, Appendix I). The risk to birds following acute and short-term exposure to the aromatic petroleum distillate in the end-use product at the maximum application rate is below the level of concern (i.e., the risk quotient was less than one).

4.2.2 Effects on Aquatic Organisms

Risk of pyroxsulam to aquatic organisms was based upon evaluation of toxicity data for six freshwater species (two invertebrates, two fish, one alga and one vascular plant); and two estuarine/marine species (one invertebrate and one alga). Risk of the transformation product 7-OH-pyroxsulam to aquatic organisms was based upon evaluation of toxicity data for five freshwater species (two invertebrates, one fish, one alga and one vascular plant). Risk of the transformation product pyroxsulam-ATSA to aquatic organisms was based upon evaluation of toxicity data for four freshwater species (one invertebrate, one fish, one alga and one vascular plant). The risk of the transformation products 5-OH-pyroxsulam, 6-Cl-7-OH-pyroxsulam, 5,7-di-OH-pyroxsulam, 742-ADTP and 742-sulfinic acid to aquatic organisms was evaluated with toxicity data for two freshwater species (one alga and one vascular plant). See Table 9, Appendix I for a summary of toxicity data reviewed.

In the freshwater environment, pyroxsulam and its transformation products 7-OH-pyroxsulam and pyroxsulam-ATSA were not acutely toxic to fish or invertebrate species; median lethal concentrations (LC_{50}s) were all greater than the test limits. Observable effects were noted following long-term exposure of invertebrates to pyroxsulam (reduced number of emerged midges at 50 mg a.i./L) and the transformation product 7-OH-pyroxsulam (reduced development rate of female midges at 30 mg/L). No effects on fish were observed following long-exposure to pyroxsulam. Pyroxsulam was toxic to green algae (EC_{50} of 0.111 mg a.i./L), while transformation products 5-OH-pyroxsulam, 6-Cl-7-OH-pyroxsulam, 5,7-di-OH-pyroxsulam, 7-OH-pyroxsulam, 742-ADTP, pyroxsulam-ATSA and 742-sulfinic acid were not toxic. The risk to invertebrates, fish and algae following short-term and long-term exposure to pyroxsulam and its transformation products at the maximum application rate is below the level of concern; risk quotients are less than one (Table 10, Appendix I).

Pyroxsulam was highly toxic to the vascular plant, Lemna gibba, which was the most sensitive aquatic organism tested. The transformation products 5-OH-pyroxsulam, 6-Cl-7-OH-pyroxsulam, 5,7-di-OH-pyroxsulam, 7-OH-pyroxsulam, 742-ADTP, pyroxsulam-ATSA and 742-sulfinic acid were not toxic. The risk quotient calculated using the maximum application rate exceeded the level of concern for pyroxsulam, but was less than one for all of the transformation products tested (Table 10, Appendix I).

A refined assessment of the risk of pyroxsulam for aquatic vascular plants considered that the most likely routes of entry of pyroxsulam into water are through drift and runoff (Table 11, Appendix I). Refined risk quotients for drift were less than one for both ground and aerial application, when taking into account the maximum drift deposition at one metre from the site of application. A one metre buffer zone is needed to mitigate against potential effects to vascular plants in adjacent aquatic habitats. The runoff assessment indicated that the highest expected runoff concentrations are lower than the concentrations at which there is negligible impact on aquatic plant communities.

The end-use product, Simplicity Herbicide, contains an aromatic petroleum distillate, which is toxic to aquatic organisms. The risk of the aromatic petroleum distillate formulant to aquatic organisms was determined for the use pattern on wheat, and was based upon toxicity data for two freshwater species (one invertebrate and one fish) (Table 12, Appendix I). The risk to amphibians following exposure to the aromatic petroleum distillate in the end-use product at the maximum application rate exceeds the level of concern (i.e., the risk quotient was greater than one).

A refined assessment of the risk of the end-use product to amphibians considered that the most likely route of entry of aromatic petroleum distillate into water is through drift and runoff (Table 13, Appendix I). Refined risk quotients for drift were less than one for both ground and aerial application, when taking into account the maximum drift deposition at one metre from the site of application. A one metre buffer zone is needed to mitigate against potential effects of the aromatic petroleum distillate in the end-use product to amphibians in adjacent aquatic habitats. Insufficient information is available to model the concentrations of aromatic petroleum distillates in runoff. Based on available physico-chemical properties of aromatic petroleum distillates, concentrations of this formulant in runoff are not expected to be high. The contribution of run-off to levels of aromatic petroleum distillates in aquatic environments is not expected to exceed the contribution from drift, for which the risk has been assessed.

5.0 Value

5.1 Effectiveness Against Pests

Data from 71 efficacy trials conducted over 2 years at several locations in Manitoba, Saskatchewan, and Alberta were submitted. For each trial, an appropriate experimental design was used, and an appropriate set of treatments was included to address the proposed pest claims. In general, the herbicide treatments were applied within the proposed growth stage range for broadleaf weeds and grass weeds using small plot application equipment.

The efficacy of Simplicity Herbicide applied as a stand-alone herbicide treatment or in tank mixtures with other herbicides for control of individual weed species was visually assessed as percent weed control and compared to an untreated weedy check. Observations were made at various times throughout the growing season.

5.1.1 Acceptable Efficacy Claims

Simplicity Herbicide Applied as a Stand-Alone Herbicide Treatment

The submitted efficacy data established the lowest effective rate for the Simplicity Herbicide treatment applied alone and support the weed control and suppression claims that are summarized in Table 5.1.1.1. Simplicity Herbicide must be applied with Assist Oil Concentrate.

Table 5.1.1.1 Weed Control and Suppression Claims for Simplicity Herbicide*

Herbicide Rate	Weeds Controlled	Weeds Suppressed
15 g a.i./ha or 500 mL product/ha	wild oats, common chickweed, cleavers, volunteer canola, hempnettle, smartweed (lady's-thumb), redroot pigweed	green foxtail, wild buckwheat

* Simplicity Herbicide must be applied with Assist Oil Concentrate at a rate of 0.8% v/v.

Herbicide Tank Mix Combinations

Adequate data were provided to support weed control and suppression claims for the proposed herbicide tank mixture of Simplicity Herbicide with each of the following tank-mix partners: Frontline Herbicide Tank-Mix (Table 5.1.1.2), Spectrum Herbicide Tank-Mix (Table 5.1.1.3), MCPA LV500 (Table 5.1.1.4), Buctril M (Table 5.1.1.5), and Refine Extra (Table 5.1.1.6). No reduction in weed control was observed when Simplicity Herbicide was tank-mixed with any of the tank-mix partners.

Table 5.1.1.2 Weed Control and Suppression Claims for Simplicity Herbicide in Tank Mix With Frontline Herbicide Tank-Mix*

Product	Rate (g a.i./ha)	Weeds Controlled	Weeds Suppressed
Simplicity Herbicide	15	wild oats, common chickweed, cleavers, volunteer canola, hempnettle, smartweed (lady's-thumb), redroot pigweed, wild buckwheat, burdock, flixweed, kochia, lamb's-quarters, ball mustard, wild mustard, Russian pigweed, prickly lettuce, common ragweed, shepherd's purse, stinkweed, annual sunflower	green foxtail, dandelion, plantain, annual sowthistle, perennial sowthistle, stork's bill, Canada thistle
Frontline Herbicide Tank-Mix	355		

* Assist Oil Concentrate must not be used when tank-mixing with a broadleaved tank-mix partner.

Table 5.1.1.3 Weed Control and Suppression Claims for Simplicity Herbicide in Tank Mix With Spectrum Herbicide Tank-Mix*

Product	Rate (g a.i./ha)	Weeds Controlled	Weeds Suppressed
Simplicity Herbicide	15	wild oats, common chickweed, cleavers, volunteer canola, hempnettle, smartweed (lady's-thumb), redroot pigweed, wild buckwheat, dandelions (seedlings), flixweed, lamb's-quarters, wild mustard, shepherd's purse, perennial sowthistle, annual sowthistle, stinkweed, stork's-bill, Canada thistle	green foxtail, dandelions
Spectrum Herbicide Tank-Mix	500		

* Assist Oil Concentrate must not be used when tank-mixing with a broadleaved tank-mix partner.

Table 5.1.1.4 Weed Control and Suppression Claims for Simplicity Herbicide in Tank Mix With MCPA LV500 Herbicide*

Product	Rate (g a.i./ha)	Weeds Controlled	Weeds Suppressed
Simplicity Herbicide	15	wild oats, common chickweed, cleavers, volunteer canola, hempnettle, smartweed (lady's-thumb), redroot pigweed, burdock, cocklebur, field pennycress, flixweed, kochia, lamb's-quarters, mustard (except dog & green tansy), prickly lettuce, ragweeds, Russian pigweed, shepherd's purse, annual sunflower, vetch, field horsetail, hoary cress, plantain	green foxtail, wild buckwheat
MCPA LV500 Herbicide	350-560**		

* Assist Oil Concentrate must not be used when tank-mixing with a broadleaved tank-mix partner.

** The lower rate is to be applied to rapidly growing seedlings; the higher rate is to be applied to weeds in bud, in dry cool weather, and under heavy infestations.

Table 5.1.1.5 Weed Control and Suppression Claims for Simplicity Herbicide in Tank Mix With Buctril M Herbicide*

Product	Rate (g a.i./ha)	Weeds Controlled	Weeds Suppressed
Simplicity Herbicide	15	wild oats, common chickweed, cleavers, volunteer canola, hempnettle, lady's-thumb, redroot pigweed, wild buckwheat, green smartweed, pale smartweed, cow cockle, flixweed, bluebur, shepherd's purse, kochia, Russian thistle, scentless chamomile, volunteer sunflower, night flowering catchfly, cocklebur, velvetleaf, ball mustard, American nightshade, wild tomato, tartary buckwheat, common buckwheat, stinkweed, wild mustard, wormseed mustard, lamb's-quarters, common ragweed, common groundsel	green foxtail, Canada thistle, perennial sow-thistle
Buctril M Herbicide	560		

* Assist Oil Concentrate must not be used when tank-mixing with a broadleaved tank-mix partner.

Table 5.1.1.6 Weed Control and Suppression Claims for Simplicity Herbicide in Tank Mix With Refine Extra Herbicide*

Product	Rate (g a.i./ha)	Weeds Controlled	Weeds Suppressed
Simplicity Herbicide	15	wild oats, common chickweed, cleavers, volunteer canola, hempnettle, lady's-thumb, redroot pigweed, wild buckwheat, green smartweed, ball mustard, corn spurry, cow cockle, flixweed, common groundsel, kochia, lamb's-quarters, narrow-leaved hawk's-beard, Russian thistle, shepherd's purse, stinkweed, tartary buckwheat, volunteer sunflower, wild mustard	green foxtail, Canada thistle, round-leaved mallow, scentless chamomile, sow thistle, stork's-bill, toadflax
Refine Extra Herbicide	15		

* Assist Oil Concentrate must not be used when tank-mixing with a broadleaved tank-mix partner, however one of the following surfactants is to be used with this tank-mix: Agral 90, Ag-Surf or Citowett Plus at 2 L per 1000 L spray solution.

5.2 Phytotoxicity to Host Plant

Data from 83 crop tolerance trials (78 trials on spring wheat and 16 trials on durum wheat) conducted over 2 years in Manitoba, Saskatchewan, and Alberta over several locations were submitted in support of the proposed host crop tolerance claims.

Crop injury was visually assessed four times during the growing season and was expressed as a percentage. Crop yield, expressed as a percentage of a weedy or weed-free check, was reported in 15 trials.

5.2.1 Acceptable Claim for Host Plant

Crop injury data with Simplicity Herbicide applied alone or in tank-mixture support a crop tolerance claim for spring wheat and durum wheat when viewed in conjunction with the crop yield data.

5.3 Impact on Succeeding Crops

Data from 12 trials that were initiated in one of three years were submitted in support of the proposed rotational crop options in the year following application of Simplicity Herbicide. Crop tolerance of all the proposed rotational crops to pyroxsulam was assessed in varying numbers of trials. Trials were conducted at five different locations in either Alberta, Saskatchewan or Manitoba. A randomized complete block design was used for all trials and treatments were replicated four times.

5.3.1 Acceptable Claims for Rotational Crops

The submitted crop injury and yield data support a rotational crop tolerance claim for the following crops planted in the year after application of Simplicity Herbicide: barley, canola, flax, lentils, oats, field peas, chickpea, spring wheat, soybeans, or summerfallow.

5.4 Economics

Not available.

5.5 Sustainability

5.5.1 Survey of Alternatives

Simplicity Herbicide applied alone, in spring wheat and durum wheat, provides consistent control of wild oats, a problematic weed in cereal crops. The key herbicide options currently available for post-emergence control of wild oats in spring and/or durum wheat are summarized in Table 5.5.1.1. These alternatives fall into three categories:

a) Group 1 herbicides that control annual grasses only,

b) Combination products that contain three active ingredients, belonging to at least 2 mode of action groups,

c) Group 2 herbicides that control wild oats and some broadleaf weeds.

Simplicity Herbicide falls into the last category. Therefore, there are three other products currently registered that belong to the same mode of action group as Simplicity Herbicide and that will provide control of wild oats, and some broadleaf weeds, in spring wheat and durum wheat.

Table 5.5.1.1 Alternative Herbicides for Wild Oats Control in Spring and/or Durum Wheat

Technical Grade Active Ingredient	End-use Products	Weed Claims	Herbicide Classification	
			Group	Mode of Action
Flucarbazone	Everest	**controls:** wild oats, green foxtail, volunteer tame oats, redroot pigweed, wild mustard, stinkweed, volunteer canola, green smartweed, & shepherd's purse	2	ALS inhibitor
Imazamethabenz	Assert	**controls:** wild oats, wild mustard, & stinkweed **suppresses**: wild buckwheat & tartary buckwheat	2	ALS inhibitor
Sulfosulfuron	Sundance (soil restrictions)	**controls:** wild oats, foxtail barley, common chickweed, wild mustard, redroot pigweed, stinkweed, volunteer canola, cleavers **suppresses:** green foxtail, quackgrass, barnyardgrass, dandelion, perennial sow-thistle	2	ALS inhibitor
thifensulfuron methyl + fenoxaprop + MCPA	Triumph Plus (spring wheat only)	wild oats, green foxtail, yellow foxtail and several broadleaf weeds	2, 1, & 4	ALS inhibitor, ACCase inhibitor & synthetic auxin
fenoxaprop-p-ethyl + bromoxynil + MCPA	Puma One Pass Post-Emergent Herbicide Tank Mix	wild oats, green foxtail, barnyard grass & many broadleaf weeds (including perennials)	1, 6, & 4	ACCase inhibitor, photosynthesis inhibitor at PSII & synthetic auxin
tralkoxydim + clopyralid + MCPA	Prevail Liquid Herbicide Tank Mix	annual grasses and broadleaf weeds	1, 4, & 4	ACCase inhibitor & synthetic auxins
clodinafop + MCPA + dicamba	Bounty Tank-Mix	annual grasses and broadleaf weeds	1, 4, & 4	ACCase inhibitor & synthetic auxin
clodinafop-propargyl	Horizon	annual grasses only	1	ACCase inhibitor
tralkoxydim	Achieve, Affirm	annual grasses only	1	ACCase inhibitor
diclofop-methyl	Hoe-Grass 284	annual grasses only	1	ACCase inhibitor
clodinafop-propargyl	Horizon	annual grasses only	1	ACCase inhibitor
fenoxaprop-p-ethyl	Puma Super	annual grasses only	1	ACCase inhibitor
Pinoxaden	Axial	annual grasses only	1	ACCase inhibitor

5.5.2 Compatibility with Current Management Practices Including Integrated Pest Management

Simplicity Herbicide offers broad-spectrum weed control when used as a postemergence herbicide in spring wheat and durum wheat. It is compatible with integrated weed management practices due to its use in controlling a range of broadleaf and grassy weeds with a single application and its postemergence application timing that permits an assessment of whether a herbicide is truly necessary or whether the product is suitable for the particular weed species present as well as its compatibility with conservation tillage and conventional production systems.

5.5.3 Information on the Occurrence or Possible Occurrence of the Development of Resistance

Repeated use of herbicides having the same mode of action in a weed control program increases the probability of naturally selecting the biotypes, a group of plants within a species which has biological traits that are not common to the population as a whole, with less susceptibility to the herbicides using that mode of action. Therefore, Simplicity Herbicide should be tank-mixed with a herbicide with a different mode of action or be used in rotation with herbicides having different modes of action. Simplicity Herbicide can be tank-mixed with florasulam + MCPA (Groups 2&4), florasulam + clopyralid + MCPA (Groups 2,4&4), MCPA (Group 4), bromoxynil + MCPA (Groups 6&4) and thifensulfuron methyl + tribenuron methyl (Group 2&2). All of these tank-mix partners would expand the broadleaf weed spectrum claim.

Using Simplicity Herbicide may reduce the dependence of growers on Group 1 chemistry. Therefore, the use of Simplicity Herbicide in combination with tank-mix partners mentioned above will provide Canadian wheat growers a new tool to manage wild oats resistance to Group 1 herbicides.

Simplicity Herbicide label includes the resistance management statements, as per Regulatory Directive DIR99-06, *Voluntary Pesticide Resistance-Management Labelling Based on Target Site/Mode of Action*.

6.0 Pest Control Product Policy Considerations

6.1 Toxic Substances Management Policy Considerations

The management of toxic substances is guided by the federal government's Toxic Substances Management Policy, which puts forward a preventive and precautionary approach to deal with substances that enter the environment and could harm the environment or human health. The policy provides decision makers with direction and sets out a science-based management framework to ensure that federal programs are consistent with its objectives. One of the key management objectives is virtual elimination from the environment of toxic substances that result predominantly from human activity and that are persistent and bioaccumulative. These substances are referred to in the policy as Track 1 substances.

During the review process, pyroxsulam was assessed in accordance with the PMRA Regulatory Directive DIR99-03, The Pest Management Regulatory Agency's Strategy for Implementing the Toxic Substances Management Policy. Substances associated with the use of pyroxsulam were also considered, including transformation products formed in the environment, and contaminants and formulants in the technical product and the end-use product. Pyroxsulam and its transformation products were evaluated against the following Track 1 criteria: persistence in soil ≥182 days; persistence in water ≥182 days; persistence in sediment ≥365 days; persistence in air ≥2 days; bioaccumulation log Kow ≥5 or BCF ≥5000 (or BAF ≥5000). In order for pyroxsulam or its transformation products to meet Track 1 criteria, the criteria for both bioaccumulation and persistence (in one media) must be met. The technical product and end-use product, including

formulants, were assessed against the contaminants identified in the Canada Gazette, Part II, Volume 139, Number 24, pages 2641–2643: List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern, Part 3 Contaminants of Health or Environmental Concern. The PMRA has reached the following conclusions:

- Pyroxsulam does not meet Track 1 criteria. Pyroxsulam meets the Track 1 criterion for persistence in sediment because it is considered stable under anaerobic conditions. It does not meet the Track 1 criterion for persistence in water, as its half-life in the water phase of aerobic water-sediment systems is 11 to 21 days, which is below the Track 1 criteria.
- Pyroxsulam does not meet the Track 1 criterion for persistence in soil because its half-life in soil based on laboratory studies (2.1 to 14.6 days) as well as field studies (5 to 72 days; 72-day half-life estimated by taking 1/3 of the 90% dissipation time of 239 days) is below the Track 1 criterion. Pyroxsulam does not meet the Track 1 criterion for persistence in air because volatilisation is not an important route of dissipation and long-range atmospheric transport is unlikely to occur based on its vapour pressure (<1 x 10-7 Pa at 20°C) and Henry's Law constant (1.34 x 10-13 atm m3/mol at 20°C). Pyroxsulam does not meet the Track 1 criterion for bioaccumulation, as its octanol-water partition coefficient (log Kow of 1.08 to -1.60, depending on pH) is below the Track 1 criterion. Although it appears the Track 1 criterion is met for persistence, the Track 1 criterion for bioaccumulation is not met. Because pyroxsulam does not meet all Track 1 criteria, it is not considered a Track 1 substance.

Pyroxsulam does not form any transformation products that meet the Track 1 criteria.

However, limited data were available to assess the TSMP Track 1 criteria for the transformation product pyroxsulam sulfonamide. Pyroxsulam sulfonamide meets the Track 1 criterion for persistence in soil (half-life of 212 days). There were no laboratory studies supplied on transformation rates for pyroxsulam sulfonamide in water or air, nor were any environmental toxicity data supplied. The log n-octanol water partition coefficient (log K_{ow}) for pyroxsulam sulfonamide was also not provided. The applicant is required to provide the log K_{ow} for pyroxsulam sulfonamide to demonstrate that this transformation product is not bioaccumulative according to TSMP Track 1 criteria.

There are no Track 1 formulants or contaminants in the technical product or end use product.

6.2 Formulants and Contaminants of Health or Environmental Concern

During the review process, contaminants in the technical and formulants and contaminants in the end-use products are assessed against the formulants and contaminants identified in the Canada Gazette, Part II, Volume 139, Number 24, pages 2641–2643: List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern. This list of formulants and contaminants of health and environmental concern are identified using existing policies and regulations including: the federal Toxic Substances Management Policy; the Ozone-depleting Substance Regulations, 1998, of the Canadian Environmental Protection Act (substances designated under the Montreal Protocol); and the PMRA Formulants Policy as described in the

PMRA Regulatory Directive DIR2006-02, Formulants Policy and Implementation Guidance Document. The List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern is maintained and used as described in the PMRA Notice of Intent NOI2005-01, List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern under the New Pest Control Products Act.

The List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern consists of three parts:

Part 1: Formulants of Health or Environmental Concern;

Part 2: Formulants of Health or Environmental Concern that are Allergens Known to Cause Anaphylactic-Type Reactions; and

Part 3: Contaminants of Health or Environmental Concern.

The contaminants to which Part 3 applies meet the federal Toxic Substances Management Policy criteria as Track 1 substances, and are considered in section 6.1. The following assessment refers to the formulants and contaminants in Part 1 and Part 2 of the list.

Technical grade pyroxsulam does not contain any contaminants of health or environmental concern identified in the Canada Gazette, Part II, Volume 139, Number 24, pages 2641–2643: List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern.

The end-use product, Simplicity Herbicide, does not contain any formulants or contaminants of health or environmental concern identified in the Canada Gazette, Part II, Volume 139, Number 24, pages 2641–2643: List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern. However, the product does contain an aromatic petroleum distillate. Therefore, the label for the end-use product Simplicity Herbicide will include the statement: “This product contains aromatic petroleum distillates that are toxic to aquatic organisms.”

7.0 Summary

7.1 Human Health and Safety

The toxicology database submitted for pyroxsulam is adequate to define the majority of toxic effects that may result from human exposure to pyroxsulam. In subchronic and chronic studies with laboratory animals, effects were limited to reduced food efficiency in dogs and liver toxicity in dogs and mice at doses exceeding the limit dose for toxicological testing. There was no evidence of carcinogenicity, neurotoxicity, or reproductive or developmental toxicity.

Mixer, loader, applicators and workers entering treated fields and greenhouses are not expected to be exposed to levels of pyroxsulam that will result in unacceptable risk when Simplicity Herbicide is used according to label directions. The personal protective equipment on the product label is adequate to protect workers, and no additional personal protective equipment is required.

The nature of the residue in wheat and animals is adequately understood. The residue definition for wheat is pyroxsulam for purposes of risk assessment and enforcement. The residue definition for animal commodities is pyroxsulam for risk assessment and enforcement. However measurable residues of pyroxsulam are not expected in animal commodities. The proposed use of pyroxsulam on wheat does not constitute an unacceptable chronic dietary risk (food and drinking water) to any segment of the population, including infants, children, adults and seniors. Sufficient crop residue data have been reviewed to recommend maximum residue limits to protect human health. The PMRA recommends that the following maximum residue limit be specified for under the authority of the Pest Control Products Act:

Wheat, grain (0.01 ppm)

7.2 Environmental Risk

Pyroxsulam and transformation products 5-OH-pyroxsulam, 6-Cl-7-OH-pyroxsulam, 5,7-di-OH-pyroxsulam, 7-OH-pyroxsulam, 742-ADTP, pyroxsulam-ATSA and 742-sulfinic acid present a negligible risk to wild mammals, birds, earthworms, bees and other arthropods, aquatic invertebrates, fish and green algae. However, given that pyroxsulam is an herbicide, it is expected to adversely affect terrestrial and aquatic vascular plants in adjacent areas. Therefore, buffer zones of 2 metres for ground application and of 55 to 65 metres for aerial application (depending on application equipment) are needed to protect terrestrial plants from the effects of spray drift of pyroxsulam to adjacent terrestrial habitats. In addition, the formulation Simplicity Herbicide contains an aromatic petroleum distillate which may affect amphibians in adjacent areas. A buffer zone of one metre is needed to protect aquatic vascular plants and amphibians from the effects of spray drift of pyroxsulam and of the aromatic petroleum distillate in the formulation Simplicity Herbicide to adjacent aquatic habitats. An assessment of the leaching potential of pyroxsulam and its transformation products indicates that these compounds have the potential to leach to groundwater. Therefore, a label statement to mitigate against leaching is required on the product label.

7.3 Value

The data submitted to register Simplicity Herbicide are adequate to describe its efficacy for use in spring wheat and durum wheat. Simplicity Herbicide provides control of wild oats, a problematic weed in cereal crops, and several broadleaf weeds with a single application to spring wheat or durum wheat. Spring wheat and durum wheat tolerance and yield response to the application of Simplicity Herbicide are also acceptable. Simplicity Herbicide provides an alternative to Group 1 herbicides, which are of concern given the spread of ACCase-resistant wild oats.

8.0 Regulatory Decision

Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and Regulations, has granted conditional registration for the sale and use of Pyroxsulam Technical Herbicide and Simplicity Herbicide, containing the technical grade active ingredient pyroxsulam, to control broadleaf and grassy weeds in spring wheat and durum wheat using ground or aerial application equipment.

An evaluation of available scientific information found that, under the approved conditions of use, the product has value and does not present an unacceptable risk to human health or the environment.

Although the risks and value have been found acceptable when all risk reduction measures are followed, the applicant must submit additional scientific information as a condition of registration. For more details, refer to the Section 12 Notice associated with these conditional registrations.

NOTE: The PMRA will publish a consultation document at the time when there is a proposed decision on applications to convert these conditional registrations to full registrations or on applications to renew the conditional registrations, whichever occurs first.

Environment

The applicant must submit the following information within one year from the registration decision.

1. Provide the octanol-water partition coefficient (log K_{ow}) for the transformation product pyroxsulam sulfonamide to determine its potential bioaccumulation under TSMP. The study should be conducted under GLP.

2. Provide a new toxicity study for pyroxsulam on the freshwater diatom, *Navicula pelliculosa*. The study must conform to standard international guidelines (e.g. USEPA, OECD) and be conducted under GLP.

Chemistry

1. Analytical data from at least five batches of the TGAI representing full-scale production.

List of Abbreviations

μg	micrograms
a.i.	active ingredient
ADI	acceptable daily intake
ASAE	American Society of Agricultural Engineers
ALS	acetolactate synthase
ARfD	acute reference dose
atm	atmosphere
bw	body weight
EEC	expected environmental concentration
ER_{25}	effective rate for 25% of the population
FDA	Food and Drugs Act
g	gram
GLP	good laboratory practice
ha	hectare(s)
HPLC	high performance liquid chromatography
kg	kilogram
K_{ow}	*n*–octanol-water partition coefficient
L	litre
LC_{50}	lethal concentration 50%
LOAEL	lowest observed adverse effect level
LOC	level of concern
mg	milligram
mL	millilitre
MAS	maximum average score
MOE	margin of exposure
MRL	maximum residue limit
MS	mass spectrometry
N/A	not applicable
NOAEL	no observed adverse effect level
PAM	pesticide analytical method
PCPA	Pest Control Products Act
PHED	pesticide handlers exposuredatabase
p*K*a	dissociation constant
PMRA	Pest Management Regulatory Agency
PPE	personal protective equipment
ppm	parts per million
RQ	risk quotient
TRR	total radioactive residue
TSMP	Toxic Substances Management Policy
UF	uncertainty factor
USEPA	United States Environmental Protection Agency
VMD	volume median diameter
v/v	volume per volume dilution

Appendix I Tables and Figures

Table 1 Residue Analysis

Matrix	Method ID	Analyte	Method Type	LOQ	Reference
Plants (including wheat)	GRM 04.17	Pyroxsulam	LC/MS/MS	0.01 ppm	1283144, 1283146
Soil/ Sediment	GRM 06.01	XDE-742	LC/MS-MS 435-195 m/z	0.03 ng/g	1283137
Soil/ Sediment	GRM 05.05	XDE-742	435-195 m/z	1.0 ng/g	1283136 to 1283140
		5-OH-XDE-742 7-OH-XDE-742 6-Cl-7-OH-XDE-742	421-181 m/z 421-181 m/z 455-215 m/z	1.0 ng/g	
Water	GRM 05.19	XDE-742	435.1-195.1 m/z	0.05 µg/L	1283141 to 1283143
		7-OH-XDE-742 ADTP ATSA Sulfunic acid Sulfonic acid	420.9-181.0 m/z 196.2-115.1 m/z 339-99.1 m/z 239.9-175.8 m/z 255.7-149.0	0.05 µg/L	

Table 2 Acute Toxicity of Pyroxsulam Technical Herbicide and Its Associated End-Use Product , Simplicity Herbicide

Study Type	Species	Result	Comment	Reference
Acute Toxicity of Pyroxsulam Technical Herbicide				
Oral	Rat	LD_{50} > 2000 mg/kg bw	Low Toxicity	1283069
Dermal	Rat	LD_{50} > 2000 mg/kg bw	Low Toxicity	1283071
Inhalation	Rat	LC_{50} > 5.12 mg/L	Low Toxicity	1470370
Skin irritation	Rabbit	MAS[a] = 0	Non-irritating	1283076
Eye irritation	Rabbit	MAS = 1.1	Minimally irritating	1283074
Skin sensitization (maximization)	Guinea pig	Positive	Potential dermal sensitizer	1283078
Acute Toxicity of End-Use Product—Simplicity Herbicide				
Oral	Rat	LD_{50} = 3129 mg/kg bw	Low Toxicity	1283329
Dermal	Rat	LD_{50} > 5000 mg/kg bw	Low Toxicity	1283331
Inhalation	Rat	LC_{50} >1.1 mg/L	Slight Toxicity	1470370

Study Type	Species	Result	Comment	Reference
Skin irritation	Rabbit	MAS = 4.8	Moderately irritating	1283336
Eye irritation	Rabbit	MAS = 34.2	Moderately Irritating	1283334
Skin sensitization (LLNA)	Guinea pig	Positive	Potential dermal sensitizer	1283338

[a] MAS = maximum average score for 24, 48 and 72 hours

Table 3 Toxicity Profile of Pyroxsulam Technical Herbicide

Study Type	Species	Results[a] (mg/kg/day)	Reference
14-day dermal	Rat	A NOAEL and LOAEL were not established as this was a range-finding study. No treatment-related effects were noted up to 1000 mg/kg bw/day.	1283122
28-day dermal	N/A	Waiver requested based on overall low toxicity by the oral route and the lack of obvious signs of toxicity by the dermal route at the limit dose of 1000 mg/kg bw/day in the 14-day range-finding study.	1283091
28-day dietary	Rat	NOAEL * 1000 mg/kg bw/day. LOAEL not established as no adverse effects were noted.	1283090
90-day dietary	Rat	NOAEL * 1000 mg/kg bw/day. LOAEL not established as no adverse effects were noted.	1283082
90-day dietary	Mouse	NOAEL * 1000 mg/kg bw/day. LOAEL not established as no adverse effects were noted.	1283081
90-day dietary	Dog	NOAEL (M) * 884 mg/kg bw/day. LOAEL (M) not established as no adverse effects were noted. NOAEL (F) = 98.6 mg/kg bw/day. LOAEL (F) = 1142 mg/kg bw/day, based on decreased body weight gain, increased food consumption, decreased overall food efficiency, increased liver weight, increased serum cholesterol, and panlobular hepatocellular hypertrophy.	1283086
1-year dietary	Dog	NOAEL * 620/589 mg/kg bw/day in M/F. LOAEL not established as no adverse effects were noted.	1283085
Carcinogenicity (2-year dietary)	Rat	NOAEL * 1000 mg/kg bw/day. LOAEL not established as no adverse effects were noted.	1283093
Carcinogenicity (18-month dietary)	Mouse	NOAEL (M) = 100 mg/kg bw/day. LOAEL (M) = 932 mg/kg bw/day, based on increased liver weight, increased incidences of liver masses/nodules, and increased incidence of foci of altered hepatocytes. NOAEL (F) * 1012 mg/kg bw/day. LOAEL not established as no adverse effects were noted.	1283095

Study Type	Species	Results[a] (mg/kg/day)	Reference
Two-generation reproduction	Rat	Parental systemic NOAEL * 1000 mg/kg bw/day. Parental systemic LOAEL not established as no adverse effects were noted. Offspring systemic NOAEL * 1000 mg/kg bw/day. Offspring systemic LOAEL not established as no adverse effects were noted. Reproductive NOAEL * 1000 mg/kg bw/day. Reproductive LOAEL not established as no adverse effects were noted.	1283100
Developmental toxicity	Rat	Maternal NOAEL * 1000 mg/kg bw/day. Maternal LOAEL not established as no adverse effects were noted. Developmental NOAEL * 1000 mg/kg bw/day. Developmental LOAEL not established as no adverse effects were noted.	1283104
Developmental toxicity (Range-finding)	Rabbit	A NOAEL and LOAEL were not established as this was a range-finding study. Maternal effects at 300 mg/kg bw/day included small faeces, decreased defecation, slightly decreased body weight (2-4%) and body weight gain (32%) during the dosing period. Maternal effects at 600 mg/kg bw/day included small faeces, decreased defecation, decreased food consumption (20%) during the dosing period, and slightly decreased body weight (3-5%) and body weight gain (43%) during the dosing period. All dams dosed with 1000 mg/kg bw/day were sacrificed due to severe body weight loss and decreased food consumption in 2/6 dams.	1283105
Developmental toxicity	Rabbit	Maternal NOAEL * 300 mg/kg bw/day. Maternal LOAEL not established as no adverse effects were noted. Developmental NOAEL * 300 mg/kg bw/day. Developmental LOAEL not established as no adverse effects were noted.	1283106
Chronic Neurotoxicity (1-year dietary)	Rat	NOAEL * 1000 mg/kg bw/day. LOAEL not established as no adverse effects were noted.	1283097
Reverse gene mutation assay	*Salmonella typhimurium/ E.coli*	Negative	1283108
In vitro mammalian chromosomal aberration	Rat lymphocytes	Negative	1283110
In vitro forward gene mutation	Chinese hamster ovary cells	Negative	1283112
In vivo mammalian cytogenetics - micronucleus assay	Mouse	Negative	1283114
In vivo/in vitro unscheduled DNA synthesis	Mouse liver	Negative	1369031

Study Type	Species	Results[a] (mg/kg/day)	Reference
Metabolism	Rat	**Absorption:** Pyroxsulam was rapidly (Cmax occurred at 30 minutes post-dosing) and highly (approximately 78% of the administered dose) absorbed following a single oral dose of 10 mg/kg bw. Saturation of absorption was observed between 10 and 1000 mg/kg bw, with absorption following dosing at 1000 mg/kg bw of approximately 30% (without knowledge of biliary excretion). **Distribution:** Radioactivity remaining in tissues/carcass 48 hours post-dosing was similar for all low dose groups (0.58-0.64% of the administered dose for the oral groups, 0.75% of the administered dose for the i.v. group) and was 0.35% of the administered dose for the single oral high dose group. In general, the liver, GIT, and kidney contained the highest levels of radioactivity, with slight differences noted for different dosing regimes. **Excretion:** Pyroxsulam was rapidly excreted, with the majority of radioactivity eliminated by 12 and 24 hours in urine and feces, respectively. At 48 hours post-dosing, 95-110% of the administered dose was recovered in excreta, tissues, and carcass. Urinary excretion accounted for 57-78% and 30% of the administered dose from all low dose groups and the high dose group, respectively. The feces accounted for 45-51% and 69% of the orally administered dose for the low dose and high dose groups, respectively. The i.v. administration demonstrated 17% excretion in the feces. Radioactivity recovered in tissues/carcass and cage wash 48 hours after dosing accounted for less than 1% and 1-3% of the orally administered dose, respectively. Radioactivity incorporated into volatile organics and CO_2 in expired air was negligible (<0.01% of the administered dose). The excretion profiles were similar following single and repeat dosing and for the two radiolabels. The single oral high dose group demonstrated less radioactivity in tissues/carcass and urine and more radioactivity in the feces compared to the single oral low dose. The i.v. dosing resulted in more radioactivity detected in urine and less in the feces compared to the single oral low dose group. **Metabolism:** Parent accounted for most of the radioactivity detected in excreta (85-90% of the administered dose). One major metabolite was identified (2-demethyl-Pyroxsulam formed through O-dealkylation) at 15-16% of the administered dose for the low dose groups and at 4% of the administered dose for the high dose group. Unidentified metabolites each accounted for less than 1.5% of the administered dose (even lower after repeat dosing). The metabolism data indicated minimal ring cleavage.	1283118

Study Type	Species	Results[a] (mg/kg/day)	Reference
Metabolism	Mouse	**Absorption:** Pyroxsulam was rapidly absorbed with maximum radioactivity detected in plasma within 0.5-2 hours post-dosing. Based on the radioactivity recovered in the urine, tissues, carcass and cage wash, and without knowledge of the biliary absorption, approximately 61-65% of the administered dose was absorbed for males from the 10 and 100 mg/kg bw and for females from the 100 mg/kg bw dose groups, while 29% of the administered dose was absorbed for the males from the 1000 mg/kg bw dose group. **Excretion:** Pyroxsulam was rapidly excreted, with the majority of the radioactivity being eliminated with 12 and 24 hours post-dosing via the urine and feces, respectively. After 72 hours, excretion was primarily via the urine (56-61% of the administered dose) for males dosed at 10 and 100 mg/kg bw and for females dosed at 100 mg/kg bw. For males dosed at 1000 mg/kg bw, 26% of the administered dose was eliminated via the urine. Fecal excretion accounted for 39-43% of the administered dose for males dosed at 10 and 100 mg/kg bw and for females dosed at 100 mg/kg bw, and 77% of the administered dose for males dosed at 1000 mg/kg bw. **Distribution:** Tissue residues increased with dose, but not proportionally. The highest levels of radioactivity were detected in the carcass, GIT, and liver. The radioactivity recovered in the tissues/carcass accounted for < 1% of the administered dose. **Metabolism:** Not determined.	1283119

a Effects observed in males as well as females unless otherwise reported

Table 4 Toxicological Endpoints for Use in Health Risk Assessment for Pyroxsulam Technical Herbicide

Exposure Scenario	Dose (mg/kg bw/day)	Study	Endpoint	UF/SF or Target MOE	Reference
Acute dietary	Not required as no endpoint of concern attributable to a single dose was identified.				
Chronic dietary, all populations	NOAEL = 100	18-month dietary study in the mouse	Increased liver weight, increased incidence of liver masses/nodules, and increased incidence of foci of altered hepatocytes.	100	1283095
ADI = 1.0 mg/kg bw/day					
Short and intermediate term dermal and inhalation	NOAEL = 100	18-month dietary study in the mouse	Increased liver weight, increased incidence of liver masses/nodules, and increased incidence of foci of altered hepatocytes.	100	1283095

Table 5 Integrated Food Residue Chemistry Summary

NATURE OF THE RESIDUE IN WHEAT			PMRA # 1283130	
Radiolabel Position	**Pyroxsulam-[^{14}C-Pyridine ring]**		**Pyroxsulam-[^{14}C-Triazolo-pyrimidinyl ring]**	
Test site	Outdoor plots			
Treatment	Immature wheat plants at BBCH 30-31 stage of growth			
Rate	37.5 g a.i./ha			
End-use product	GF-1274			
Preharvest interval	0 and 7 d for forage; 51 d for hay; and 92 d for grain and straw.			
Matrix	**PHI (days)**	**Pyroxsulam-[^{14}C-Pyridine ring]**	**Pyroxsulam-[^{14}C-Triazolo-pyrimidinyl ring]**	
		TRR (ppm)		
Plants at BBCH 30 -31 stage of growth	0	1.960	1.266	
Early forage	7	0.707	0.203	
Hay	51	0.111	0.081	
Straw	92	0.034	0.023	
Grain	92	0.001	<0.002	
Matrix	**Major Metabolites (> 10% TRRs)**		**Minor Metabolites (< 10% TRRs)**	
	Pyroxsulam-[^{14}C-Pyridine ring]	**Pyroxsulam-[^{14}C-Triazolo-pyrimidinyl ring]**	**Pyroxsulam-[^{14}C-Pyridine ring]**	**Pyroxsulam-[^{14}C-Triazolo-pyrimidinyl ring]**
Forage (0 d)	Pyroxsulam	Pyroxsulam	Sulfonamide	-
Forage (7 d)	5-OH-XDE-742, 5-OH-XDE-742 conjugate	5-OH-XDE-742, 5-OH-XDE-742 conjugate	Pyroxsulam, 7-OH-XDE-742, Sulfonamide, Sulfonic acid	Pyroxsulam, 5,7-di-OH-XDE-742, ADTP
Hay (51 d)	5-OH-XDE-742 conjugate	5-OH-XDE-742, 5-OH-XDE-742 conjugate	Pyroxsulam, 5-OH-XDE-742, Sulfonic acid	Pyroxsulam, 7-OH-XDE-742
Straw (92 d)	-	-	-	-
Grain (92 d)	-	-	-	-
Pyroxsulam is metabolized by demethylation of the 5 or 7 ether group of the pyridine ring to form 5-OH-XDE-742 or 7-OH-XDE-742. The presence of ADTP, sulfonic acid, and sulfonamide metabolites is indicative of cleavage of pyroxsulam on either side of the sulfonamide nitrogen. Pyroxsulam was metabolized rapidly.				

CONFINED ACCUMULATION IN ROTATIONAL CROPS - Potatoes, Lettuce, Wheat			**PMRA # 1283366**
Radiolabel Position		**Pyroxsulam-[^{14}C-Pyridine ring]**	**Pyroxsulam-[^{14}C-Triazolo-pyrimidinyl ring]**
Test site		Confined outdoor plots of sandy loam soil	
Formulation used for trial		Radiolabelled materials dissolved in acetonitrile	
Application rate and timing		18.75 g a.i./ha applied 30 d before planting of rotational crops (Potatoes, lettuce, and wheat)	
Matrix	**PBI, days**	**Overall TRRs (ppm)**	
		Pyroxsulam-[^{14}C-Pyridine ring]	**Pyroxsulam-[^{14}C-Triazolo-pyrimidinyl ring]**
Potato tops-mature	30	0.036	0.003
Potato tubers-mature	30	0.001	<0.0005 (LOQ)
Lettuce-mature	30	0.006	0.001
Wheat forage	30	0.002	0.001
Wheat hay	30	0.020	0.003
Wheat grain	30	0.001	0.001
Wheat straw	30	0.023	0.006
Matrix	**PBI (days)**	**Major Metabolites (> 10% TRR)**	**Minor Metabolites (< 10% TRR)**
		Pyroxsulam-[^{14}C-Pyridine ring]	
Soil (0 d)	NA	Pyroxsulam	-
Soil (7 d)	NA	Pyroxsulam, 7-OH-XDE-742	5-OH-XDE-742
Potato tops-mature	30	Pyroxsulam-cyanosulfonamide, 5-OH-XDE-742	-
Wheat hay	30	7-OH-XDE-742, 6-Cl-7-OH-XDE-742	Pyroxsulam-cyanosulfonamide
Wheat straw	30	-	7-OH-XDE-742

Following uptake of pyroxsulam by rotational crops, initial metabolism results in the formation of 5-OH-XDE-742 and 7-OH-XDE-742. These two metabolites could also be taken up from soil into plant tissue. It was proposed that 7-OH-XDE-742 is transformed to 6-Cl-OH-XDE-742 in plant tissue. The presence of pyroxsulam-cyanosulfonamide indicates cleavage across the triazolo ring.

(It is noted that all rotational crops from plots treated with pyroxsulam-[^{14}C-Triazolo-pyrimidinyl ring] had TRRs that were too low for further characterization/identification. Furthermore, mature potato tubers, mature lettuce, and wheat forage and grain from pyroxsulam-[^{14}C-Pyridine ring] treated plots had TRRs that were too low for further characterization/identification.)

NATURE OF THE RESIDUE IN LAYING HEN	PMRA # 1283125

Leghorn laying hens were dosed for 7 consecutive days with pyroxsulam radiolabelled in either the pyridine or the triaolo-pyrimidinyl rings at 10 mg a.i./kg feed/d in the diet (equivalent to 0.839 mg a.i./kg bw/d). Hens were sacrificed within 24 h of the final dose. There were ten hens per treatment group.

Matrix	% of the Administered Dose	
	Pyroxsulam-[^{14}C-Pyridine ring]	Pyroxsulam-[^{14}C-Triazolo-pyrimidinyl ring]
Excreta	104	97.2
Muscle	<0.01	<0.01
Fat	<0.01	<0.01
Liver	<0.01	<0.01
Egg	<0.01	<0.01

Matrix	Major Metabolites (> 10% TRR)		Minor Metabolites (< 10% TRR)	
	Pyroxsulam-[^{14}C-Pyridine ring]	Pyroxsulam-[^{14}C-Triazolo-pyrimidinyl ring]	Pyroxsulam-[^{14}C-Pyridine ring]	Pyroxsulam-[^{14}C-Triazolo-pyrimidinyl ring]
Liver	Pyroxsulam	Pyroxsulam	-	742-ADTP
Excreta	Pyroxsulam	Pyroxsulam	5-OH-XDE-742, 7-OH-XDE-742	5-OH-XDE-742, 7-OH-XDE-742

Pyroxsulam is mostly excreted (>90 % of applied dose) from laying hens over the course of this study. The presence of 5-OH-XDE-742 and 7-OH-XDE-742 in excreta is indicative of demethylation of the 5 or 7 ether groups of the pyrimidine ring. The presence of 742-ADTP in the liver of hens that were administered pyroxsulam-[^{14}C-Triazolo-pyrimidinyl ring] is indicative of cleavage at the sulfonamide nitrogen of pyroxsulam.

NATURE OF THE RESIDUE IN LACTATING GOAT	PMRA # 1283124

Lactating goats (Bunte deutsche Edelziege) were dosed for 7 consecutive days with radiolabelled pyroxsulam by gavage at 12 mg a.i./kg feed/d in the diet (equivalent to 0.4 mg a.i./kg bw/d). The goats were sacrificed within 24 h of the receiving the last dose. One goat was dosed with pyroxsulam-[^{14}C-Pyridine ring] and another with pyroxsulam-[^{14}C-Triazolo-pyrimidinyl ring].

Matrix	% of Administered Dose	
	Pyroxsulam-[^{14}C-Pyridine ring]	Pyroxsulam-[^{14}C-Triazolo-pyrimidinyl ring]
Urine, feces, and cage wash	92.04	83.44
Muscle	0.010	0.004
Fat	0.001	0.001
Kidney	0.002	0.001
Liver	0.013	0.008
Milk	0.028	0.026

NATURE OF THE RESIDUE IN LACTATING GOAT		PMRA # 1283124	
Matrices	**Major Metabolites (> 10% TRR)**		**Minor Metabolites (< 10% TRR)**	
	Pyroxsulam-[^{14}C-Pyridine ring]	**Pyroxsulam-[^{14}C-Triazolo-pyrimidinyl**	**Pyroxsulam-[^{14}C-Pyridine ring]**	**Pyroxsulam-[^{14}C-Triazolo-pyrimidinyl**
Liver	Pyroxsulam	Pyroxsulam	5,7-di-OH-XDE-742	-
Kidney	Pyroxsulam	Pyroxsulam	5,7-di-OH-XDE-742	-
Milk	Pyroxsulam	Pyroxsulam	-	-
Urine	Pyroxsulam	Pyroxsulam	7-OH-XDE-742, 5,7-di-OH-XDE-742	7-OH-XDE-742, 5,7-di-OH-XDE-742
Feces	Pyroxsulam	Pyroxsulam	7-OH-XDE-742	7-OH-XDE-742
A majority of the administered dose was excreted (≥ 83 %). The petitioner reported that pyroxsulam is not significantly metabolized.				

STORAGE STABILITY	PMRA #s 1501700, 1283173
In one study, plant commodities (spinach, tomato, potato, soybean, wheat grain, wheat straw, and wheat forage) were spiked with pyroxsulam at 0.10 ppm and were stored for 6 months at -20°C. Pyroxsulam was stable in all commodities. Specifically, mean recoveries of pyroxsulam ranged from 96-108 % after 6 months of frozen storage. In another study, the same plant commodities noted above were spiked with either cloquintocet-mexyl or cloquintocet-acid at 0.10 ppm and were stored for 9 months at -20°C. Both analytes were stable for 9 months in all matrices tested. Specifically, mean recoveries for each plant commodity ranged from 78-95% and from 88-99% for cloquintocet-mexyl and cloquintocet-acid, respectively, after 9 months.	

CROP FIELD TRIALS ON WHEAT									PMRA # 1283364
During the 2005 growing season, twenty field trials were conducted in Canada (2 trials in Zone 5; 5 trials in Zone 7; 3 trials in Zone 7A;10 trials in Zone14) to evaluate the magnitude of the residues of pyroxsulam, cloquintocet-mexyl, and cloquintocet-acid in/on wheat following one foliar application of the end-use product GF-1674 OD Herbicide.									
Commodity	**Total Applic. Rate (g a.i./ha)**	**PHI (days)**	**Residue Levels (ppm)**						
			n	**Min.**	**Max.**	**HAFT**	**Median (STMdR)**	**Mean (STMR)**	**Std. Dev.**
Pyroxsulam									
Forage	14.3-15.6	7-14	40	<0.010	0.036	0.035	<0.010	<0.010	<0.007
Hay		28-43	40	<0.010	<0.010	<0.010	<0.010	<0.010	-
Grain		50-110	40	<0.010	<0.010	<0.010	<0.010	<0.010	-
Straw		50-110	40	<0.010	<0.010	<0.010	<0.010	<0.010	-
Cloquintocet-mexyl									
Forage	0.8 % cloquintocet-mexyl	7-14	40	<0.010	<0.010	<0.010	<0.010	<0.010	-
Hay		28-43	40	<0.010	<0.010	<0.010	<0.010	<0.010	-
Grain		50-110	40	<0.010	<0.010	<0.010	<0.010	<0.010	-
Straw		50-110	40	<0.010	<0.010	<0.010	<0.010	<0.010	-

CROP FIELD TRIALS ON WHEAT							PMRA # 1283364		
Cloquintocet-acid									
Forage	0.8 % cloquintocet-mexyl	7-14	40	<0.010	<0.010	<0.010	<0.010	<0.010	-
Hay		28-43	40	<0.010	0.027	0.026	<0.011	<0.013	<0.005
Grain		50-110	40	<0.010	<0.010	<0.010	<0.010	<0.010	-
Straw		50-110	40	<0.010	0.034	0.031	<0.010	<0.012	<0.005

PROCESSED FOOD AND FEED	PMRA # Not submitted
A processing study is not required on the basis of the crop field trials on wheat (PMRA # 1283364) and the wheat metabolism study (PMRA # 1283130). Specifically, when wheat was treated at the proposed label rate (15 g a.i./ha), residues of pyroxsulam were <0.01 ppm (LOQ, Method GRM 04.17) in grain harvested at 50-110 d PHIs in the crop field trials. Furthermore, TRRs were <0.002 ppm in grain when treated at a rate of 2.5X greater than the proposed label rate and harvested at a 92 d PHI in the wheat metabolism study. Therefore, residues in commodities processed from wheat grain are not expected.	

LIVESTOCK FEEDING – Dairy cattle and Laying hens	PMRA # Not submitted
Livestock feeding studies are not required on the basis of the lactating goat and laying hen metabolism studies (PMRA #s 1283124, 1283125) and the wheat crop field trial study (PMRA # 1283364). Specifically, residues in feed items were estimated from the maximum residues of pyroxsulam in/on wheat fractions from the crop field trial study. These values were used along with the TRRs from the livestock metabolism studies to extrapolate the maximum residues expected in livestock commodities. Using this approach, it was estimated that maximum residues in livestock commodities are expected to be <0.0002 ppm for the proposed use in/on wheat.	

Table 6 Food Residue Chemistry Overview of Metabolism Studies and Risk Assessment

PLANT STUDIES	
RESIDUE DEFINITION FOR ENFORCEMENT **Primary crops - Wheat** **Rotational crops**	**Pyroxsulam**
RESIDUE DEFINITION FOR RISK ASSESSMENT **Primary crops** **Rotational crops**	**Pyroxsulam**
METABOLIC PROFILE IN DIVERSE CROPS	**Metabolism in wheat is understood.**
ANIMAL STUDIES	
ANIMALS	**Ruminant**
RESIDUE DEFINITION FOR ENFORCEMENT	**Pyroxsulam**
RESIDUE DEFINITION FOR RISK ASSESSMENT	**Pyroxsulam**
METABOLIC PROFILE IN ANIMALS (goat, hen, rat)	**Metabolism in ruminants and poultry is similar.**
FAT SOLUBLE RESIDUE	**No**

DIETARY RISK FROM FOOD AND WATER			
	POPULATION	**ESTIMATED RISK % of ACCEPTABLE DAILY INTAKE (ADI)**	
		Food Only	**Food and Water**
Refined chronic non-cancer dietary risk **ADI = 1.0 mg/kg bw** **Estimated chronic drinking water concentration = 23.4 µg/L**	All infants < 1 year	0.0	0.2
	Children 1–2 years	0.0	0.1
	Children 3 to 5 years	0.0	0.1
	Children 6–12 years	0.0	0.1
	Youth 13–19 years	0.0	0.0
	Adults 20–49 years	0.0	0.0
	Adults 50+ years	0.0	0.0
	Total population	0.0	0.1

Table 7 Fate and Behaviour in the Environment

Study Type	Test Substance	Value	Comments	Reference
Terrestrial Environment				
Abiotic Transformation				
Hydrolysis	^{14}C-TP-pyroxsulam and ^{14}C-Py-pyroxsulam (triazolopyrimidine ring and pyridine ring)	Stable in water at pH 5, 7 and 9, at 20°C	Stable to hydrolysis at environmentally relevant pH levels.	1283151
Phototransformation	^{14}C-TP-pyroxsulam and ^{14}C-Py-pyroxsulam	Stable on silt loam soil, pH 6.2, 2.1% OM	Stable to phototransformation on soils (transformation in dark controls was greater than in the irradiated samples)	1283153
Biotransformation				
Biotransformation in aerobic soil	^{14}C-TP-pyroxsulam and ^{14}C-Py-pyroxsulam	Pyroxsulam: $t_{1/2}$, $t_{9/10}$ of both radiolabels combined: light clay soil: 3.8, 12.6 days clay loam: 2.1, 6.8 days loamy sand: 10.0, 33.3 days sandy loam: 2.7, 9.1 days 5-OH-pyroxsulam: $t_{1/2}$, $t_{9/10}$: clay loam: 9.1, 21.5 days sandy loam: 9.6, 22.5 days	Half-lives from this study not used in the risk assessment Pyroxsulam: Non-persistent in aerobic soils 5-OH-pyroxsulam: Non-persistent 7-OH-pyroxsulam: moderately persistent to persistent, based on 1/3 DT_{90} estimates 6-Cl-7-OH-pyroxsulam: slightly persistent, based on 1/3 DT_{90} estimate	1283157

Study Type	Test Substance	Value	Comments	Reference
		7-OH-pyroxsulam: DT_{50}, DT_{90}, 1/3 DT_{90}: light clay: 16.5, 246.2, 74.2 days loamy sand: 85.6 days, not reached, stable 6-Cl-7-OH-pyroxsulam: DT_{50}, DT_{90}, 1/3 DT_{90} light clay: 25.2, 126.8, 38.2 days		
	^{14}C-TP-pyroxsulam and ^{14}C-Py-pyroxsulam	Pyroxsulam: $t_{1/2}$, $t_{9/10}$ of both radiolabels combined: clay loam: 3.7, 12.4 days clay loam: 2.1, 6.8 days sandy loam: 14.6, 48.4 days sandy loam: 5.0, 16.8 days 5-OH-pyroxsulam: $t_{1/2}$, $t_{9/10}$: clay loam: 9.0, 27.5 days 7-OH-pyroxsulam: $t_{1/2}$, $t_{9/10}$: sandy loam: 68.4, 236.5 days 6-Cl-7-OH-pyroxsulam: DT_{50}, DT_{90}, 1/3 DT_{90} in soil where dissipation did not follow simple first order kinetics: clay loam: 11.3 days, not reached, stable $t_{1/2}$, $t_{9/10}$ in soil where dissipation followed simple first order kinetics: sandy loam: 69.4, 192.5 days Pyroxsulam sulfonamide: $t_{1/2}$, $t_{9/10}$: clay loam: 212, 640 days	Exhaustive extraction methods used. Results from this study used in the risk assessment Pyroxsulam is non-persistent to slightly persistent in aerobic soils 5-OH-pyroxsulam: Non-persistent 7-OH-pyroxsulam: moderately persistent 6-Cl-7-OH-pyroxsulam: moderately persistent to persisent based on $t_{1/2}$ and 1/3 DT_{90} estimates Pyroxsulam sulfonamide: persistent	1450772

Study Type	Test Substance	Value	Comments	Reference
	non-radiolabelled pyroxsulam	soils where dissipation followed simple first order kinetics; clay loam, loamy sand (x 2), sandy loam (x 7), sandy clay loam, light clay (x 2): $t_{1/2}$: 0.8-16.7 days $t_{9/10}$: 3.3-55.4 days soils where dissipation did not follow simple first order kinetics; sandy loam, light clay (x 2): DT_{50}: 1.5-12.2 days DT_{90}: 5.7-57.3 days 1/3 DT_{90}: 1.7-17.3 days	Half-lives from this study not directly used in the risk assessment Pyroxsulam is non-persistent to slightly persistent based on $t_{1/2}$ and 1/3 DT_{90} estimates	1283159
	^{14}C-5,7-di-OH-pyroxsulam	DT_{50}, DT_{90}, 1/3 DT_{90}: loamy sand: 0.19, 15, 4.5 days loamy sand: 0.37, 8, 2.4 days light clay: 0.10, 9, 2.7 days sandy clay loam: 0.14, 3, 0.9 days	Not stable in aerobic soil	1283160
Biotransformation in anaerobic soil		Not submitted.	Pyroxsulam will be assumed stable under anaerobic conditions.	
Mobility				
Adsorption/desorption	^{14}C-Py-pyroxsulam	Non-Freundlich coefficients in silt loam, sandy loam (x 5), loamy sand (x 2), clay loam and loam: $K_{d\text{-}ads}$: 0.19-1.76 mL/g $K_{OC\text{-}ads}$: 7.1-54.3 mL/g	High to very high mobility	1283169
	^{14}C-5-OH-pyroxsulam	Non-Freundlich coefficients in loam, sandy loam (x 2) and loamy sand: $K_{d\text{-}ads}$: 0.053-0.322 mL/g $K_{OC\text{-}ads}$: 2-22 mL/g	Very high mobility	1283168

Study Type	Test Substance	Value	Comments	Reference
	^{14}C-7-OH-pyroxsulam	Non-Freundlich coefficients in silt loam, sandy loam (x 5), loamy sand (x 2), clay loam and loam: $K_{d\text{-}ads}$: 0.502-1.408 mL/g $K_{OC\text{-}ads}$: 20-108 mL/g	High to very high mobility	1283168
	^{14}C-5,7-di-OH-pyroxsulam	Non-Freundlich coefficients in silt loam, sandy loam (x 5), loamy sand (x 2), clay loam and loam: $K_{d\text{-}ads}$: 1.333-5.923 mL/g $K_{OC\text{-}ads}$: 53-557 mL/g	Low to high mobility	1283168
	^{14}C-6-Cl-7-OH-pyroxsulam	Non-Freundlich coefficients in loam, sandy loam (x 2) and loamy sand: $K_{d\text{-}ads}$: 0.35-1.057 mL/g $K_{OC\text{-}ads}$: 14-81 mL/g	High to very high mobility	1283168
	^{14}C-pyroxsulam pyridine sulfonic acid	Non-Freundlich coefficients in loam, sandy loam (x 2) and loamy sand: $K_{d\text{-}ads}$: could not be calculated $K_{OC\text{-}ads}$: could not be calculated	Very high mobility	1283168
	^{14}C-pyroxsulam cyanosulfonamide	Non-Freundlich coefficients in loam, sandy loam (x 2) and loamy sand: $K_{d\text{-}ads}$: could not be calculated -0.098 mL/g $K_{OC\text{-}ads}$: could not be calculated-10 mL/g	Very high mobility	1283168
Soil leaching		Not submitted.	Adsorption / desorption studies provided information on mobility.	
Volatilization		Not submitted.	Not volatile and no additional studies needed.	

Study Type	Test Substance	Value	Comments	Reference
Field studies				
Field dissipation	GF-1442 (4.7% pyroxsulam)	Alberta Pyroxsulam (dissipation did not follow simple first order kinetics): DT_{50}: 29 days; DT_{90}: 239 days 1/3 DT_{90}: 72 days 7-OH-pyroxsulam: $t_{1/2}$: 97 days; $t_{9/10}$: 321 days 6-Cl-7-OH-pyroxsulam: $t_{1/x}$: 84 days; $t_{9/10}$: 279 days Pyroxsulam detected down to 15-30 cm; 7-OH-pyroxsulam detected down to 15-30 cm; 6-Cl-7-OH-pyroxsulam detected down to 45-60 cm Carry over to the next growing season (370 DAT) was 10%, 23% and 6% for pyroxsulam, 7-OH-pyroxsulam and 6-Cl-7-OH-pyroxsulam, respectively	Pyroxsulam is moderately persistent, based on 1/3 DT_{90} estimate 7-OH-pyroxsulam and 6-Cl-7-OH-pyroxsulam are moderately persistent	1283372
		Saskatchewan, site 1 Pyroxsulam: $t_{1/2}$: 5 days; $t_{9/10}$: 15 days 7-OH-pyroxsulam: $t_{1/2}$: 3 days; $t_{9/10}$: 10 days Pyroxsulam residues detected down to 15-30 cm. Transformation products detected down to 0-15 cm. Carry over of pyroxsulam to the next growing season was 1%; no carry over of transformation products.	Pyroxulam and 7-OH-pyroxsulam are non-persistent	1283372

Study Type	Test Substance	Value	Comments	Reference
		Saskatchewan, site 2 Pyroxsulam: $t_{1/2}$: 5 days; $t_{9/10}$: 15 days 7-OH-pyroxsulam: $t_{1/2}$: 6 days; $t_{9/10}$: 21 days Pyroxsulam detected down to 15-30 cm; transformation products detected down to 0-15 cm. No carry over of residues to the next growing season.	Pyroxulam and 7-OH-pyroxsulam are non-persistent	1283372
		Manitoba Pyroxsulam: $t_{1/2}$: 13 days; $t_{9/10}$: 44 days 7-OH-pyroxsulam: $t_{1/2}$: 21 days; $t_{9/10}$: 70 days Pyroxsulam detected down to 45-60 cm; 7-OH-pyroxsulam detected down to 15-30 cm. Pyroxsulam carry over at the end of the study (126 DAT): 4%. No carry over of transformation products.	Pyroxsulam in non-persistent 7-OH-pyroxsulam is slightly persistent	1283372
Field leaching		Not submitted.	Not required.	
Aquatic systems				
Hydrolysis	^{14}C-TP-pyroxsulam and ^{14}C-Py-pyroxsulam (triazolopyrimidine ring and pyridine ring)	Stable in water at pH 5, 7 and 9, at 20°C	Stable to hydrolysis at environmentally relevant pH levels.	1283151
Phototransformation in water	^{14}C-TP-pyroxsulam and ^{14}C-Py-pyroxsulam	Predicted environmental half-life: 4.5 days at 40°N latitude in summer sunlight	Important route of transformation in the photic zone of aquatic systems.	1283155
Biotransformation in aerobic water-sediment systems	^{14}C-TP-pyroxsulam and ^{14}C-Py-pyroxsulam	sandy clay loam system Pyroxsulam: whole system $t_{1/2}$: 24 days; $t_{9/10}$: 44 days	Pyroxsulam and 7-OH-pyroxsulam are slightly persistent, and pyroxsulam-	1283166

Study Type	Test Substance	Value	Comments	Reference
		7-OH-pyroxsulam: whole system $t_{1/2}$: 16 days; $t_{9/10}$: 52 days pyroxsulam-ATSA: whole system $t_{1/2}$: 71 days; $t_{9/10}$: 237 days	ATSA is moderately persistent in aerobic whole water-sediment system.	
		sand system Pyroxsulam: whole system $t_{1/2}$: 12 days; $t_{9/10}$: 40 days 7-OH-pyroxsulam: whole system $t_{1/2}$: 42 days; $t_{9/10}$: 141 days pyroxsulam-ATSA: whole system $t_{1/2}$: 22 days; $t_{9/10}$: 73 days	Pyroxsulam, 7-OH-pyroxsulam and pyroxsulam-ATSA are slightly persistent in aerobic whole water-sediment system.	1283166
Biotransformation in anaerobic water-sediment systems	^{14}C-TP-pyroxsulam and ^{14}C-Py-pyroxsulam	silt loam system Pyroxsulam was stable for the first 30 days. Transformation occurred subsequently, likely as a result of a change in dissolved oxygen and redox conditions. Pyroxsulam is assumed to be stable under anaerobic conditions.	Considered persistent.	1283164
Field dissipation		Not submitted.	Not required.	

Table 8 Transformation products of pyroxsulam in the environment

Fate process	Test Material	Major transformation products (>10% of applied radioactivity)	Minor transformation products
Hydrolysis	^{14}C-TP-pyroxsulam and ^{14}C-Py-pyroxsulam (triazolopyrimidine ring and pyridine ring)	None.	None.
Phototransformation on soil	^{14}C-TP-pyroxsulam and ^{14}C-Py-pyroxsulam	No transformation products attributed to phototransformation.	No transformation products attributed to phototransformation.
Phototransformation in water	^{14}C-TP-pyroxsulam and ^{14}C-Py-pyroxsulam	742-sulfinic acid (79.2%, day 3.8) 742-ADTP (39.8%, day 3.8)	Pyroxsulam pyridine sulfonic acid (<LOQ; Py label only) multiple unknown products (49-69% in irradiated samples, study end) Volatile compounds (1.2%, day 14.9)

Fate process	Test Material	Major transformation products (>10% of applied radioactivity)	Minor transformation products
Biotransformation in aerobic soil	Pyroxsulam study 1: ^{14}C-TP-pyroxsulam and ^{14}C-Py-pyroxsulam	5-OH-pyroxsulam (24%, day 3) 7-OH-pyroxsulam (13%, day 7) 6-Cl-7-OH-pyroxsulam (26%, day 7) CO_2 (5-15% at study end) NER (60-90% at study end)	pyroxsulam cyanosulfonamide (8%, day 21) pyroxsulam pyridine sulfonic acid (6%, day 29, Py label only)
	Pyroxsulam study 2 (exhaustive extraction): ^{14}C-TP-pyroxsulam and ^{14}C-Py-pyroxsulam	5-OH-pyroxsulam (24.4%, day 4) 6-Cl-7-OH-pyroxsulam (11%, day 7) pyroxsulam-sulfonamide (13.2%, day 29) CO_2 (11%, study end) NER (37.9-82.8% study end)	7-OH-pyroxsulam (7.9%, day 14) pyroxsulam cyanosulfonamide (0.7%, day 63) pyroxsulam pyridine sulfonic acid (3.6%, day 100, Py label only)
	Pyroxsulam study 3: non-radiolabelled pyroxsulam	Not determined.	Not determined.
	^{14}C-5,7-di-OH-pyroxsulam	Not determined.	Not determined.
Biotransformation in anaerobic soil (flooded soil)		No study submitted. Pyroxsulam is assumed stable under anaerobic conditions.	No study submitted. Pyroxsulam is assumed stable under anaerobic conditions.
Field dissipation	Alberta: GF-1442 (4.7% pyroxsulam)	7-OH-pyroxsulam (41% day 68)	6-Cl-7-OH-pyroxsulam (6-7%, day 68-462)
	Saskatchewan site 1: GF-1442 (4.7% pyroxsulam)	None.	5-OH-pyroxsulam (2%, day 7) 7-OH-pyroxsulam (8%, day 7) 6-Cl-7-OH-pyroxsulam (1%, day 14, 35, 370)
	Saskatchewan site 2: GF-1442 (4.7% pyroxsulam)	None.	7-OH-pyroxsulam (4%, day 14) 6-Cl-7-OH-pyroxsulam (3%, day 14)
	Manitoba: GF-1442 (4.7% pyroxsulam)	None.	7-OH-pyroxsulam (2%, day 62)
Biotransformation in aerobic water-sediment systems	sandy clay loam system: ^{14}C-TP-pyroxsulam and ^{14}C-Py-pyroxsulam	7-OH-pyroxsulam (40%, day 33) unknown transformation product (16%, day 101) NER (65.3-73.1%, study end)	pyroxsulam-ATSA (6%, day 33) volatile compounds (0.7-1.3%)
	sand system: ^{14}C-TP-pyroxsulam and ^{14}C-Py-pyroxsulam	pyroxsulam-ATSA (13%, day 54) 7-OH-pyroxsulam (58%, day 17) unknown transformation product (16%, day 33) NER (32.8-42.3%)	volatile compounds (0.2-0.6%)

Fate process	Test Material	Major transformation products (>10% of applied radioactivity)	Minor transformation products
Biotransformation in anaerobic water-sediment systems	^{14}C-TP-pyroxsulam and ^{14}C-Py-pyroxsulam	silt loam system Transformation products formed are likely as a result of an increase in redox potential. Pyroxsulam is considered stable under anaerobic conditions. 7-OH-pyroxsulam (68.1%, day 74/78) 5,7-di-OH-pyroxsulam (27.1%, study end)	None.
Field dissipation		Not submitted.	Not required.

Figure 1 Transformation pathway for pyroxsulam (XDE-742) in aerobic soil

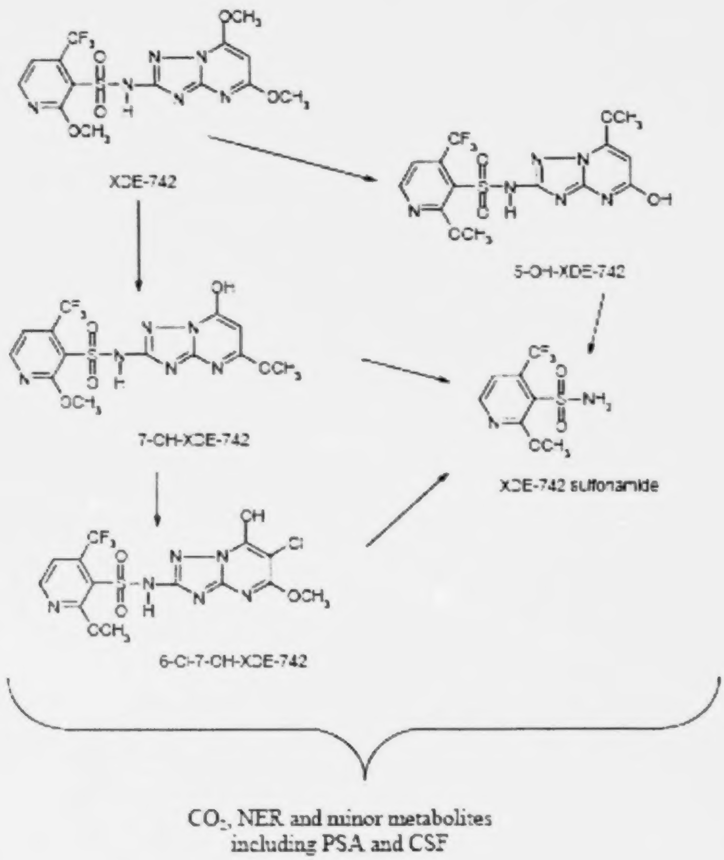


Figure 2 **Transformation pathway for pyroxsulam (XDE-742) in aerobic water-sediment systems**

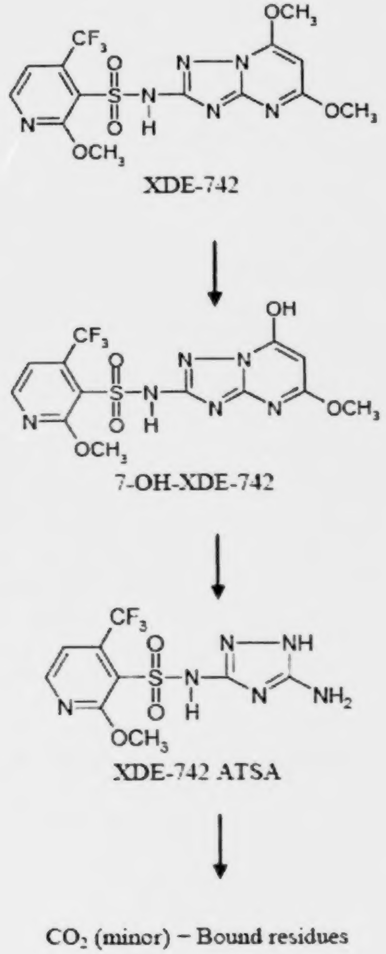


Table 9 Toxicity to Non-Target Species

Organism	Exposure	Test substance	Endpoint value	Degree of toxicity	Reference
Terrestrial Invertebrates					
Earthworm	Acute (artificial soil)	pyroxsulam	NOEC (weight loss) < 10,000 mg a.i./kg soil LC_{50} > 10,000 mg a.i./kg soil	No classification	1283187
		7-OH-pyroxsulam	NOEC (weight loss) < 62.5 mg/kg soil LC_{50} > 1000 mg/kg soil	No classification	1283182
		5-OH-pyroxsulam	NOEC = 1000 mg/kg soil LC_{50} > 1000 mg/kg soil	No classification	1283180
		6-Cl-7-OH-pyroxsulam	NOEC = 1000 mg/kg soil LC_{50} > 1000 mg/kg soil	No classification	1283181
	Chronic (artificial soil)	6-Cl-7-OH-pyroxsulam	NOEC (reproduction) = 0.065 mg/kg soil	No classification	1283275
Bee	Oral	pyroxsulam	NOEC = 107.4 µg a.i./bee LC_{50} > 107.4 µg a.i./bee (i.e.,LC_{50} > 102.3 kg a.i./ha)	Relatively non-toxic	1283188
	Contact	pyroxsulam	NOEL = 100 µg a.i./bee LD_{50} > 100 µg a.i./bee (i.e.,LC_{50} > 112 kg a.i./ha)	Relatively non-toxic	1283188
Birds					
Bobwhite quail	Acute	pyroxsulam	NOEL = 2105 mg a.i./kg bw LD_{50} > 2105 mg a.i./kg bw	Practically non-toxic	1283218
	Dietary	pyroxsulam	NOEC = 4883 mg a.i./kg diet LC_{50} > 4883 mg a.i./kg diet	Practically non-toxic	1283222
	Reproduction	pyroxsulam	NOEC = 1142 mg a.i./kg diet (Highest concentration tested)	No classification	1283226
Mallard duck	Acute	pyroxsulam	NOEL = 2030 mg a.i./kg bw LD_{50} > 2030 mg a.i./kg bw	Practically non-toxic	1283220
	Dietary	pyroxsulam	NOEC = 4840 mg a.i./kg diet LC_{50} > 4840 mg a.i./kg diet	Practically non-toxic	1283224
	Reproduction	pyroxsulam	NOEC (female weight and 14-day old duckling weight) = 499 mg a.i./kg diet	No classification	1283228
Mammals					
Rat	Acute	pyroxsulam	NOAEL = 2000 mg a.i./kg bw LD_{50} > 2000 mg a.i./kg bw	Practically non-toxic	1283069
	Dietary (90-Day; with 28-day recovery)	pyroxsulam	NOAEL = 1000 mg a.i./kg bw.d (Highest doses tested)	Practically non-toxic	1283282
	2-Generation Reproduction	pyroxsulam	NOAEL = 1000 mg a.i./kg bw/d (Highest dose tested)	No classification	1283100

Organism	Exposure	Test substance	Endpoint value	Degree of toxicity	Reference
	Developmental toxicity	pyroxsulam	NOAEL = 1000 mg a.i./kg bw/d (Highest dose tested)	No classification	1283014
	Acute	GF-1674 OD Herbicide (29 g a.i./L)	NOAEL (mortality) = 1750 mg/kg bw LD_{50} = 3129 mg/kg bw	Practically non-toxic	1283329
Mouse	Dietary (90-Day)	pyroxsulam	NOAEL = 1000 mg a.i./kg bw/d (Highest dose tested)	Practically non-toxic	1283081
Rabbit	Developmental toxicity	pyroxsulam	NOAEL = 300 mg a.i./kg bw/d (Highest dose tested)	No classification	1283106
Terrestrial Vascular Plants					
Vascular plant	Seedling emergence	GF-1674 OD Herbicide (29 g a.i./L)	ER_{25} (onion, shoot fresh weight) = 0.25 g a.i./ha ER_{50} (onion, shoot fresh weight) = 0.418 g a.i./ha	No classification	1283252
	Vegetative vigour	GF-1674 OD Herbicide (29 g a.i./L)	ER_{25} (soybean, shoot height) = 0.185 g a.i./ha ER_{50} (soybean, shoot fresh weight) = 0.856 g a.i./ha	No classification	1283253
	Post-emergence herbicidal activity screening study	Pyroxsulam, 7-OH-pyroxsulam, 5-OH-pyroxsulam, 5,7-di-OH-pyroxsulam, 6-Cl-7-OH-pyroxsulam, pyroxsulam cyanosulfonamide, pyroxsulam sulfonic acid	Pyroxsulam demonstrated significant herbicidal activity to all test species at all tested rates (3.91 to 62.5 mg/L) under the conditions of the study. All transformation products tested had little or no effect up to and including 62.5 mg/L, the highest rate tested.	No classification	1283254
Aquatic Invertebrates					
Daphnia magna	Acute	pyroxsulam	NOEC = 100 mg a.i./L EC_{50} > 100 mg a.i./L	Practically non-toxic	1283197
		7-OH-pyroxsulam	NOEC = 99 mg/L EC_{50} > 99 mg/L	At worst, slightly toxic	1283191
		pyroxsulam-ATSA	NOEC = 121 mg/L EC_{50} > 121 mg/L	Practically non-toxic	1283192
	Chronic	pyroxsulam	NOEC = 10.4 mg a.i./L No effects	No classification	1283199
Chironomus riparius	Chronic	pyroxsulam	NOEC (number of emerged midges) = 50 mg a.i./L (i.e., = 29 mg a.i./L in pore water) EC_{50} > 100 mg a.i./L (i.e., > 57 mg a.i./L in pore water)	No classification	1283204

Organism	Exposure	Test substance	Endpoint value	Degree of toxicity	Reference
·		7-OH-pyroxsulam	NOEC (female development rate) = 30 mg/L (i.e., = 12.6 mg/L in pore water) EC_{50} > 120 mg/L (i.e., > 50.4 mg/L in pore water)	No classification	1283200
Aquatic Vertebrates					
Rainbow trout	Acute	pyroxsulam	NOEC = 87 mg a.i./L LC_{50} > 87 mg a.i./L	At worst, slightly toxic	1283207
		7-OH-pyroxsulam	NOEC = 120 mg/L LC_{50} > 120 mg/L	Practically non-toxic	1283206
		pyroxsulam-ATSA	NOEC = 119 mg/L LC_{50} > 119 mg/L	Practically non-toxic	1283208
Fathead minnow	Acute	pyroxsulam	NOEC = 94.4 mg a.i./L LC_{50} > 94.4 mg a.i./L	At worst, slightly toxic	1283212
	Chronic (Early Life Stage test)	pyroxsulam	NOEC = 10.1 mg a.i./L No effects	No classification	1283215
Freshwater Algae / Plants					
Green algae (*Pseudokirchneriella subcapitata*)	Acute	pyroxsulam	NOEC = 0.026 mg a.i./L EC_{50} (cell density) = 0.135 mg a.i./L	No classification	1283249
		5-OH-pyroxsulam	EC_{50} > 42 mg/L	No classification	1283231
		7-OH-pyroxsulam	NOEC = 16 mg/L EC_{50} > 40 mg/L	No classification	1283233
		6-Cl-7-OH-pyroxsulam	EC_{50} > 39 mg/L	No classification	1283232
		5-7-di-OH-pyroxsulam	NOEC = 36 mg/L EC_{50} >36 mg/L	No classification	1283230
		742-ADTP	NOEC = 92 mg/L EC_{50} >92 mg/L	No classification	1283234
		pyroxsulam-ATSA	NOEC < 3.1 mg/L EC_{50} (biomass) = 16.8 mg/L	No classification	1283235
		742-sulfinic acid	NOEC = 55 mg/L EC_{50} (cell density) = 85 mg/L	No classification	1283246
Vascular plant (*Lemna gibba*)	Acute (1- and 3-Day Exposures)	pyroxsulam	1-Day NOEC = 1.06 μg a.i./L EC_{50} > 31.2 μg a.i./L 3-Day NOEC < 1.06 μg a.i./L EC_{50} (frond number) = 4.68 μg a.i./L	No classification	1283263
	Acute	pyroxsulam	NOEC = 0.681 μg a.i./L EC_{50} (frond number) = 2.57 μg a.i./L	No classification	1283273

Organism	Exposure	Test substance	Endpoint value	Degree of toxicity	Reference
		5-OH-pyroxsulam	NOEC = 1.7 mg/L EC_{50} (frond number) = 5.7 mg/L	No classification	1283258
		7-OH-pyroxsulam	NOEC = 0.74 mg/L EC_{50} (frond number) = 1.8 mg/L	No classification	1283260
		6-Cl-7-OH-pyroxsulam	NOEC = 16 mg/L EC_{50} (frond number) = 29 mg/L	No classification	1283259
		5-7-di-OH-pyroxsulam	NOEC = 1.7 mg/L EC_{50} > 95 mg/L	No classification	1283257
		742-ADTP	NOEC = 93 mg/L EC_{50} > 93 mg/L	No classification	1283261
		pyroxsulam-ATSA	NOEC = 120 mg/L EC_{50} > 120 mg/L	No classification	1283262
		742-sulfinic acid	NOEC = 110 mg/L EC_{50} > 110 mg/L	No classification	1283273
Estuarine/Marine Species					
Marine diatom (*Skeletonema costatum*)	Acute	pyroxsulam	NOEC = 3.4 mg a.i./L EC_{50} (cell density) = 13.1 mg a.i./L	No classification	1283251

Table 10 Screening Level Risk Assessment on Non-target Species

Organism	Exposure: Test Substance	Endpoint Value	EEC[a,b]	RQ[c]	Level of Concern
Terrestrial Invertebrates					
Earthworm	Acute: pyroxsulam	NOEC (weight loss) < 10,000 mg/kg soil	0.0067 mg a.i./kg soil	>0.0000007	A risk to earthworms is not expected at the proposed use rate.
	Acute: 7-OH-pyroxsulam	NOEC (weight loss) < 62.5 mg/kg soil	0.0065 mg/kg soil	>0.0001	A risk to earthworms is not expected at the proposed use rate.
	Acute: 5-OH-pyroxsulam	NOEC = 1000 mg/kg soil	0.0065 mg/kg soil	0.000007	Not exceeded
	Acute: 6-Cl-7-OH-pyroxsulam	NOEC = 1000 mg/kg soil	0.007 mg/kg soil	0.000007	Not exceeded
	Chronic: 6-Cl-7-OH-pyroxsulam	NOEC = 0.065 mg/kg soil	0.007 mg/kg soil	0.1	Not exceeded
Bee	Oral: pyroxsulam	LC_{50} > 107.4 μg a.i./bee (i.e., LC_{50} > 102.3 kg a.i./ha)	0.015 kg a.i./ha	< 0.0002	Not exceeded

Organism	Exposure: Test Substance	Endpoint Value	EEC[a,b]	RQ[c]	Level of Concern
	Contact: pyroxsulam	$LD_{50} > 100$ µg a.i./bee (i.e., $LC_{50} > 112$ kg a.i./ha)	0.015 kg a.i./ha	< 0.0001	Not exceeded
Birds					
Bobwhite quail	Acute: pyroxsulam	NOEL = 2105 mg a.i./kg bw	0.17 mg a.i./kg bw[d]	0.00008	Not exceeded
	Dietary: pyroxsulam	NOEC = 4883 mg a.i./kg diet	2.63 mg a.i./kg diet	0.0005	Not exceeded
	Reproduction: pyroxsulam	NOEC = 1142 mg a.i./kg diet	2.63 mg a.i./kg diet	0.002	Not exceeded
Mallard duck	Acute: pyroxsulam	NOEL = 2030 mg a.i./kg bw	0.088 mg a.i./kg bw[e]	0.00004	Not exceeded
	Dietary: pyroxsulam	NOEC = 4840 mg a.i./kg diet	0.51 mg a.i./kg diet	0.0001	Not exceeded
	Reproduction: pyroxsulam	NOEC = 499 mg a.i./kg diet	0.51 mg a.i./kg diet	0.001	Not exceeded
Mammals					
Rat	Acute: pyroxsulam	NOAEL = 2000 mg a.i./kg bw	1.3 mg/kg bw[f]	0.0007	Not exceeded
	Dietary: pyroxsulam	NOAEL = 1000 mg a.i./kg bw/d (i.e., 5833 mg/kg diet)[g]	7.57 mg/kg dw diet	0.001	Not exceeded
	Reproduction: pyroxsulam	NOAEL = 1000 mg a.i./kg bw/d (i.e., 5833 mg/kg diet)[g]	7.57 mg/kg dw diet	0.001	Not exceeded
	Developmental: pyroxsulam	NOAEL = 1000 mg a.i./kg bw/d (i.e., 5833 mg/kg diet)[g]	7.57 mg/kg dw diet	0.001	Not exceeded
	Acute: GF-1674 OD Herbicide	NOAEL = 1750 mg/kg bw	45.1 mg/kg bw[h]	0.03	Not exceeded
Mouse	Dietary: pyroxsulam	NOAEL = 1000 mg a.i./kg bw/d (i.e., 5500 mg/kg diet)[i]	7.52 mg/kg dw diet	0.001	Not exceeded
Rabbit	Dietary: pyroxsulam	NOAEL = 300 mg a.i./kg bw/d (i.e., 10,000 mg/kg diet)[j]	11.32 mg/kg dw diet	0.001	Not exceeded
Terrestrial Vascular Plants					
Vascular plant	Seedling emergence: GF-1674 OD Herbicide	$ER_{25} = 0.25$ g a.i./ha	15 g a.i./ha	60	EXCEEDED
	Vegetative vigour: GF-1674 OD Herbicide	$ER_{25} = 0.185$ g a.i./ha	15 g a.i./ha	81.1	EXCEEDED

Organism	Exposure: Test Substance	Endpoint Value	EEC[a,b]	RQ[c]	Level of Concern
Aquatic Invertebrates					
Daphnia magna	Acute: pyroxsulam	1/2 EC_{50} > 50 mg a.i./L	0.0019 mg a.i/L	0.000004	Not exceeded
	Acute: 7-OH-pyroxsulam	1/2 EC_{50} > 44.5 mg/L	0.0018 mg/L	0.00004	Not exceeded
	Acute: pyroxsulam-ATSA	1/2 EC_{50} > 60.5 mg/L	0.0015 mg/L	0.00003	Not exceeded
	Chronic: pyroxsulam	NOEC = 10.4 mg a.i./L	0.0019 mg a.i./L	0.0002	Not exceeded
Chironomus riparius	Chronic: pyroxsulam	NOEC = 50 mg a.i./L (i.e., NOEC = 29 mg a.i./L in pore water)	0.0019 mg a.i./L	Overlying water: 0.00004 Pore water: 0.00007	Not exceeded
	Chronic: 7-OH-pyroxsulam	NOEC = 30 mg/L (i.e., NOEC = 12.6 mg/L in pore water)	0.0018 mg/L	Overlying water: 0.00006 Pore water: 0.0001	Not exceeded
Aquatic Vertebrates					
Rainbow trout	Acute: pyroxsulam	1/10 LC_{50} > 8.7 mg a.i./L	0.0019 mg a.i./L	0.0002	Not exceeded
	Acute: 7-OH-pyroxsulam	1/10 LC_{50} > 12 mg/L	0.0018 mg/L	0.0002	Not exceeded
	Acute: pyroxsulam-ATSA	1/10 LC_{50} > 11.9 mg/L	0.0015 mg/L	0.0001	Not exceeded
Fathead minnow	Acute: pyroxsulam	1/10 LC_{50} > 9.44 mg a.i./L	0.0019 mg a.i./L	0.0002	Not exceeded
	Chronic: pyroxsulam	NOEC = 10.1 mg a.i./L	0.0019 mg a.i./L	0.0002	Not exceeded
Amphibians	Acute: pyroxsulam	1/10 LC_{50} > 8.7 mg a.i./L[k]	0.01 mg a.i./L	0.001	Not exceeded
	Acute: 7-OH-pyroxsulam	1/10 LC_{50} > 12 mg/L[j]	0.0097 mg/L	0.0008	Not exceeded
	Acute: pyroxsulam-ATSA	1/10 LC_{50} > 11.9 mg/L[j]	0.0015 mg/L	0.0007	Not exceeded
	Chronic: pyroxsulam	NOEC = 10.1 mg a.i./L[j]	0.01 mg a.i./L	0.001	Not exceeded
Freshwater Algae / Plants					
Green algae (*Pseudokirchneriella subcapitata*)	Acute: pyroxsulam	1/2 EC_{50} = 0.056 mg a.i./L	0.0019 mg a.i./L	0.03	Not exceeded
	Acute: 5-OH-pyroxsulam	1/2 EC_{50} > 21 mg/L	0.0018 mg/L	0.00009	Not exceeded
	Acute: 7-OH-pyroxsulam	1/2 EC_{50} > 20 mg/L	0.0018 mg/L	0.00009	Not exceeded

Organism	Exposure: Test Substance	Endpoint Value	EEC[a,b]	RQ[c]	Level of Concern
	Acute: 6-Cl-7-OH-pyroxsulam	1/2 EC_{50} > 19.5 mg/L	0.002 mg/L	0.0001	Not exceeded
	Acute: 5-7-di-OH-pyroxsulam	1/2 EC_{50} > 18 mg/L	0.0018 mg/L	0.0001	Not exceeded
	Acute: 742-ADTP	1/2 EC_{50} > 46 mg/L	0.0009 mg/L	0.00002	Not exceeded
	Acute: pyroxsulam-ATSA	1/2 EC_{50} = 8.4 mg/L	0.0015 mg/L	0.0002	Not exceeded
	Acute: 742-sulfinic acid	1/2 EC_{50} = 42.5 mg/L	0.0011 mg/L	0.00003	Not exceeded
Vascular plant (*Lemna gibba*)	Acute: pyroxsulam	1/2 EC_{50} = 0.00129 mg a.i./L	0.0019 mg/L	1.5	EXCEEDED
	Acute: 5-OH-pyroxsulam	1/2 EC_{50} = 2.85 mg/L	0.0018 mg/L	0.0006	Not exceeded
	Acute: 7-OH-pyroxsulam	1/2 EC_{50} = 0.9 mg/L	0.0018 mg/L	0.0002	Not exceeded
	Acute: 6-Cl-7-OH-pyroxsulam	1/2 EC_{50} = 14.5 mg/L	0.002 mg/L	0.0001	Not exceeded
	Acute: 5-7-di-OH-pyroxsulam	1/2 EC_{50} > 47.5 mg/L	0.0018 mg/L	0.00004	Not exceeded
	Acute: 742-ADTP	1/2 EC_{50} > 46.5 mg/L	0.0009 mg/L	0.00002	Not exceeded
	Acute: pyroxsulam-ATSA	1/ 2 EC_{50} > 60 mg/L	0.0015 mg/L	0.00003	Not exceeded
	Acute: 742-sulfinic acid	1/2 EC_{50} > 55 mg/L	0.0011 mg/L	0.00002	Not exceeded
Estuarine/Marine Species					
Marine diatom (*Skeletonema costatum*)	Acute: pyroxsulam	1/2 EC_{50} = 6.55 mg a.i./L	0.0019 mg a.i./L	0.0003	Not exceeded

a EECs for transformation products based on assumed 100% conversion of pyroxsulam and a molar ratio of 0.97 (420.3 g/mol 5-OH-pyroxsulam / 434.4 g/mol pyroxsulam) for 5-OH-pyroxsulam, 0.97 (420.3 g/mol 7-OH-pyroxsulam / 434.4 g/mol pyroxsulam) for 7-OH-pyroxsulam, 1.05 (454.77 g/mol 6-Cl-7-OH-pyroxsulam / 434.4 g/mol pyroxsulam) for 6-Cl-7-OH-pyroxsulam, 0.78 (338.27 g/mol pyroxsulam-ATSA / 434.4 g/mol pyroxsulam) for pyroxsulam-ATSA, 0.94 (406.3 g/mol 5,7-di-OH-pyroxsulam / 434.4 g/mol pyroxsulam) for 5,7-di-OH-pyroxsulam, 0.56 (241.19 g/mol 742 sulfinic acid / 434.4 g/mol pyroxsulam) for 742-sulfinic acid, and 0.45 (195.2 g/mol 742-ADTP / 434.4 g/mol pyroxsulam) for 742-ADTP. For example, 0.0067 mg a.i./kg soil x 0.97 = 0.0065 mg 7-OH-pyroxsulam/kg soil.

b EEC in food items for birds and mammals is estimated according to a nomogram developed by the USEPA from data of Hoerger and Kenaga (1972) and Kenaga (1973), and modified according to Fletcher et al. (1994).

c Risk quotient = exposure / toxicity

d EEC according to body weight = 2.63 mg a.i./kg dw diet for bobwhite quail x 0.0189 kg dw diet/day for daily food intake rate (Nagy, 1987) / 0.178 kg for body weight (Dunning, 1993)

[e] EEC according to body weight = 0.51 mg a.i./kg dw diet for mallard duck x 0.0612 kg dw diet/day for daily food intake rate (Nagy, 1987) / 1.082 kg for body weight (Dunning, 1993)

[f] EEC according to body weight = 7.57 mg a.i./kg dw diet for rat x 0.060 kg dw diet/day for daily food intake rate (U.S. EPA, 1988) / 0.35 kg for body weight (U.S. EPA, 1988)

[g] NOAEL according to concentration in diet = 1000 mg/kg bw/day for rat x 0.35 kg bw for body weight (U.S. EPA, 1988) / 0.060 kg dw diet/day for daily food intake (U.S. EPA, 1988)

[h] EEC according to body weight = 262.9 mg EP/kg dw diet for rat x 0.060 kg dw diet/day for daily food intake rate (U.S. EPA, 1988) / 0.35 kg for body weight (U.S. EPA, 1988)

[i] NOAEL according to concentration in diet = 1000 mg/kg bw/day for mouse x 0.033 kg bw for body weight (U.S. EPA, 1988) / 0.0060 kg dw diet/day for daily food intake (U.S. EPA, 1988)

[j] NOAEL according to concentration in diet = 300 mg/kg bw/day for rabbit x 2.0 kg bw for body weight (U.S. EPA, 1988) / 0.060 kg dw diet/day for daily food intake (U.S. EPA, 1988)

[k] Risk to amphibians is based on the most sensitive fish toxicity endpoint, in a water body 15 cm deep.

Table 11 Refined Risk Assessment for Pyroxsulam on Non-Target Vascular Plant Species

Organism	Exposure: Test Substance	Endpoint Value	EEC	RQ[a]	Risk Characterization
Terrestrial Vascular Plants					
Vascular plant	Seedling emergence: Simplicity Herbicide	ER_{25} = 0.25 g a.i./ha	**Drift Assessment:** Ground application: 0.45 g a.i./ha Aerial application: 2.55 g a.i./ha	1.8 10.2	Buffer zones are required to mitigate the risk to non-target terrestrial vascular plants. Buffer zones have been calculated and added on the label under the Directions for Use.
	Vegetative vigour: Simplicity Herbicide	ER_{25} = 0.185 g a.i./ha	**Drift Assessment:** Ground application: 0.45 g a.i./ha Aerial application: 2.55 g a.i./ha	2.4 13.8	Buffer zones are required to mitigate the risk to non-target terrestrial vascular plants. Buffer zones have been calculated and added on the label under the Directions for Use.
Aquatic Vascular Plants					
Lemna gibba	Acute: pyroxsulam	1/2 ER_{50} = 0.00129 mg a.i./L	**Drift Assessment:** Ground application: 0.000056 mg a.i./L Aerial application: 0.000319 mg a.i./L	0.4 0.3	Level of concern not exceeded for either aerial or ground application. A buffer zone of 1metre is required to mitigate potential risk from drift to aquatic vascular plants. Buffer zones have been added on the label under the Directions for Use.
			Runoff: 0.000213 mg a.i./L	0.2	Level of concern not exceeded.

[a] Risk quotient = exposure / toxicity

Table 12 Screening Level Risk Assessment for the Aromatic Petroleum Distillate Formulant on Non-target Species

Organism	Exposure: Test Substance	Endpoint Value	EEC[a,b]	RQ[c]	Level of Concern
Terrestrial Species					
Bobwhite quail	Acute: Aromatic Petroleum Distillate	NOEL = 486 mg/kg bw	7.24 mg/kg bwd	0.02	Not exceeded
	Dietary: Aromatic Petroleum Distillate	NOEC = 842 mg/kg diet	68.2 mg/kg dw diet	0.08	Not exceeded
Aquatic Species					
Daphnia magna	Acute: Aromatic Petroleum Distillate	1/2 EC_{50} > 0.475 mg/L	0.049 mg/L	0.1	Not exceeded
Rainbow trout	Acute: Aromatic Petroleum Distillate	1/10 LC_{50} = 0.234 mg/L	0.049 mg/L	0.21	Not exceeded
Amphibians	Acute: Aromatic Petroleum Distillate	1/10 LC_{50} = 0.234 mg/L[e]	0.26 mg/L	1.11	EXCEEDED

a EEC in food items for birds estimated according to a nomogram developed by the USEPA from data of Hoerger and Kenaga (1972) and Kenaga (1973), and modified according tc Fletcher et al. (1994).

b EEC for aquatic habitats based on application rate of 389.7 g/ha aromatic petroleum distillate to a 1 ha pond 80 cm deep for rainbow trout and 15 cm deep for amphibians.

c Risk quotient = exposure / toxicity

d EEC according to body weight = 68.2 mg/kg dw diet for bobwhite quail x 0.0189 kg dw diet/day for daily food intake rate (Nagy, 1987) / 0.178 kg for body weight (Dunning, 1993)

e Based on endpoint from fish study to determine risk to amphibians in a 15 cm deep water body.

Table 13 Refined Risk Assessment for the Aromatic Petroleum Distillate Formulant on Non-target Amphibians

Organism	Exposure: Test Substance	Endpoint Value	EEC	RQ[a]	Risk Characterization
Amphibians	Acute: pyroxsulam	1/10 LC_{50} = 0.234 mg a.i./L[b]	**Drift Assessment** Aerial application: 0.0442 mg/L	0.2	Level of concern not exceeded for either aerial or ground application.
			Ground application: 0.0078 mg/L	0.03	A buffer zone of 1metre is required to mitigate potential risk from drift to amphibians. Buffer zones have been added on the label under the Directions for Use.
			Runoff: Not modelled	not calculated	Modelling for the Aromatic Petroleum Distillate is not possible. Contribution from runoff is not expected to exceed that from drift.

a Risk quotient = exposure / toxicity

b Based on endpoint from fish study to determine risk to amphibians in a 15 cm deep water body.

Appendix II Supplemental Maximum Residue Limit Information—International Situation and Trade Implications

Table 1 Comparison of Canadian MRLs for Pyroxsulam With Other Jurisdictions

Commodity	Canada (ppm)	US (ppm)	Codex* (ppm)
Wheat, grain	0.01	0.01	Not reviewed by Codex

* Codex is an international organization under the auspices of the United Nations that develops international food standards, including MRLs.

References

A. List of Studies/Information Submitted by Registrant

1.0 Chemistry

1283058	2006, XDE-742 Technical Active Ingredient, N /A, MRID: N/A, DACO 2.1,2.2,2.3,2.3.1,2.4,2.5,2.6,2.7,2.8,2.9 CBI
1283059	2006, Study Profile Template (SPT) for Product Chemistry Data of XDE-742 Technical, a Technical Grade Active Ingredient, NAFST-06-096, MRID: N/A, DACO: 2.11.1,2.11.2,2.11.3,2.11.4,2.12,2.12.1,2.13.1,2.13.2,2.13.3,2.13.4 CBI
1283060	2006, Group A - Product Identity and Composition, Description of Materials to Produce the Product, Description of the Production Process, Discussion of Formation of Impurities, Preliminary Analysis, Certified Limits, and Enforcement Analytical Method for
1283061	2005, Analytical Method and Validation for the Determination of Active Ingredient and Process Impurities in XDE-742 Technical by Liquid Chromatography, DECO ML-AL MD-2005-001924, MRID: N/A, DACO: 2.13.1 CBI
1283062	2005, Analytical Method and Validation for the Determination of Active Ingredient in XDE-742 Technical by Liquid Chromatography, DECO ML-AL MD-2005-002453, MRID: N/A, DACO: 2.13.1 CBI
1283063	2005, Analytical Method and Validation for the Determination of Residual Solvent in XDE-742 Technical by Gas Chromatography, DAS-AM05-038, MRID: N/A, DACO: 2.13.1 CBI
1283064	2006, Analysis of Product Samples for Active Ingredient and Impurities in Technical Grade XDE-742, FOR-05-070, MRID: N/A, DACO: 2.13.3 CBI
1283065	2006, Group B: Physical and Chemical Properties of XDE-742, NAFST-06-086, MRID: N/A, DACO: 2.14.1, 2.14.10,2.14.11,2.14.12, 2.14.13,2.14.2,2.14.3,2.14.4, 2.14.5,2.14.6,2.14.7,2.14.8,2.14.9 CBI
1283066	2006, XDE-742 Storage Stability, N/A, MRID: N/A, DACO: 2.14.14 CBI
1423162	DACO: 2.0
1283317	2006, GF-1674 - End-Use Product - Applicant, Formulator, Trade and Other Names, N/A, MRID: N/A, DACO: 3.1.1,3.1.2,3.1.3,3.1.4 CBI

1283318 2006, Group A - Product Identity, Composition and Analysis for GF-1674, an Oil Dispersion End-Use Product Containing XDE-742 and Cloquintocet-mexyl, NAFST-06-101, MRID: N/A, DACO: 3.1.3,3.1.4,3.2.1,3.2.2,3.2.3,3.3.1,3.4.1 CBI

1283319 2006, Study Profile Template for End Use Product Chemistry Data of GF-1674 Containing 30 g/L XDE-742 Active Ingredient, 06-944.SPT, MRID: N/A, DACO: 3.1.3,3.1.4,3.2.1,3.2.2,3.2.3,3.3.1, 3.4.1,3.5.1,3.5.10,3.5.11,3.5.12,3.5.13,3.5.14, 3.5.15,3.5.2,3.5.3,3.5.

1283320 2006, Validation of an Analytical Method for the Determination of XDE-742, Cloquintocet-mexyl in GF-1361, GF-1364, GF-1274 and GF-1674 and Florasulam in GF-1361 and GF-1364, DAS-AM-05-032, MRID: N/A, DACO: 3.4.1 CBI

1283321 2006, Physical and Chemical Properties of GF-1674 (30 g/L XDE-742 Active Ingredient and 90 g/L Cloquintocet-mexyl as safener) OD Formulation, 05-805-G, MRID: N/A, DACO: 3.5.1,3.5.10,3.5.12,3.5.2,3.5.3,3.5.6,3.5.7,3.5.9 CBI

1283322 2006, GF-1674 OD Herbicide - Storage Stability & Corrosion Characteristics, N/A, MRID: N/A, DACO: 3.5.10,3.5.14 CBI

1283323 2006, GF-1674 (30 g/L XDE-742, 90 g/L cloquintocet-mexyl) Eight Week 40¿¿C Stability in and Compatibility with PET Bottle Packaging, 05-809-G, MRID: N/A, DACO: 3.5.10,3.5.14 CBI

1283324 2005, Determination of Flammability (solids), Explosive Properties, Relative Self-Ignition Temperature for Solids and Oxidizing Properties for XDE-742, NAFST840, MRID: N/A, DACO: 3.5.11,3.5.12

1283325 2006, Determination of the Explosive Properties of GF-1674, FAPC 0052-013, MRID: N/A, DACO: 3.5.12 CBI

1283326 2006, GF-1674 OD Herbicide - Formulation Type, N/A, MRID: N/A, DACO: 3.5.4 CBI

1283327 2006, GF-1674 OD Herbicide -Container Material & Description, N/A, MRID: N/A, DACO: 3.5.5 CBI

1315686 DACO: 3.0

1369036 2006, GF-1674 (2.87% w/w pyroxsulam active, 8.6% w/w cloquintocet-mexyl safener) One Year Ambient Stability in an Compatibility with Fluorinated High Density Polyethylene Packaging, 05-811-G, MRID: N/A, DACO: 3.5.10,3.5.14 CBI

1283136 2006, Method Validation Report for the Determination of Residues of XDE-742 and its Metabolites in Soil and Sediment by Liquid Chromatography with Tandem Mass Spectrometry Detection Using Dow AgroSciences Method GRM 05.05, 041024, MRID: N/A, DACO: 8.2.2.1

1283137 2006, Method Validation Report for the Determination of Residues of XDE-742 in Soil and Sediment by Liquid Chromatography with Tandem Mass Spectrometry Detection Using Dow AgroSciences Method GRM 06.01, 051038, MRID: N/A, DACO: 8.2.2.1,8.2.2.2

1283138 2006, Study Profile Template for the Validation Report for Method GRM 05.05 - Determination of Residues of XDE-742 and its Metabolites in Soil and Sediment by Liquid Chromatography with Tandem Mass Spectrometry, 041024.SPT, MRID: N/A, DACO: 8.2.2.1,8.2.2

1283139 2006, Study Profile Template for the Validation Report Method GRM 06.01 - Determination of Residues of XDE-742 in Soil and Sediment by Liquid Chromatography with Tandem Mass Spectrometry, 051038, MRID: N/A, DACO: 8.2.2.1,8.2.2.2

1283140 2006, XDE-742: Independent Laboratory Validation of Dow AgroSciences LLC Analytical Method GRM 05.05 - Determination of Residues of XDE-742 and its Metabolites in Soil and Sediment by Liquid Chromatography with Tandem Mass Spectrometry Detection Using Do

1283141 2006, Independent Laboratory Validation of Dow AgroSciences LLC Method GRM 05.19 - Determination of Residues of XDE-742 and its Metabolites in Drinking Water, Ground Water, and Surface Water by Liquid Chromatography with Tandem Mass Spectrometry Detection

1283142 2006, Study Profile Template (SPT) for the Validation Report for Method GRM 05.19 - Determination of Residues of XDE-742 and its Metabolites in Drinking Water, Ground Water, and Surface Water by Liquid Chromatography with Tandem Mass Spectrometry, 051039.

1283143 2006, Validation Report for Method GRM 05.19 - Determination of Residues of XDE-742 and its Metabolites in Drinking Water, Ground Water, and Surface Water by Liquid Chromatography with Tandem Mass Spectrometry, 051039, MRID: N/A, DACO: 8.2.2.3

2.0 Human and Animal Health

1283124 2005, Investigation of the Nature and Identity of Metabolites of [14C] XDE-742 in Goat Tissues, 206430, MRID: N/A, DACO: 6.2

1283125 2005, Nature of the Residue Study in Laying Hens Using 14C-XDE-742, 040001, MRID: N/A, DACO: 6.2

1283130 2005, The Metabolism of [14C]-XDE-742 in Wheat, 804764, MRID: N/A, DACO: 6.3

1283144 2006, Method Validation Report for the Determination of Residues of XDE-742 in Agricultural Commodities by Liquid Chromatography with Tandem Mass Spectrometry Using Dow AgroSciences LLC Method GRM. 04-17, 041026, MRID: N/A, DACO: 7.2.1,7.2.2,8.2.2.4

1283146 2005, Independent laboratory Validation of Dow AgroSciences LLC Method GRM. 04-17 - Determination of Residues of XDE-742 in Agricultural Commodities by Liquid Chromatography with Tandem Mass Spectrometry, 040095, MRID: N/A, DACO: 7.2.3,8.2.2.4

1283147 2006, Independent Laboratory Validation of XDE-742: Assessment and Validation of the European Multi-Residue Enforcement Method(s) for the Determination of XDE-742 in Plant Material, Foodstuffs of Animal Origin, Soil and Body Fluids, 050045, MRID: N/A, DA

1283149 2005, XDE-742: Assessment and Validation of European Multi Residue Enforcement Method(s) for the Determination of XDE-742 in Plant Materials, in Foodstuffs of Animal Origin, in Soil, and in Body Fluids, 051001, MRID: N/A, DACO: 7.2.4,8.2.2.4

1283173 2006, Cloquintocet-mexyl and its Acid Metabolite: Freezer Storage Stability in Plant Materials and in Soil, P847G, MRID: N/A, DACO: 7.3,8.6

1283174 2006, Freezer Storage Stability in Plant Materials (XDE-742) and in Soil (XDE-742 and Three of its Metabolites), P846G, MRID: N/A, DACO: 7.2.1,7.2.5,7.3

1283350 2006, Method Validation Report for the Determination of Cloquintocet-mexyl and its Acid Metabolite in Wheat Using Enviro-Test Laboratories Method M313, ETL04DOW05, MRID: N/A, DACO: 7.2.1

1283352 2005, Cloquintocet-mexyl: Independent Laboratory Validation of an Analytical Method for the Determination of Cloquintocet-mexyl and its Acid Metabolite in Cereal, 040096, MRID: N/A, DACO: 7.2.3

1283359 2005, PAM I Multiresidue Testing for XDE-742, 051012, MRID: N/A, DACO: 7.2.4

1283364 2006, Residues of XDE-742 and the Safener, Cloquintocet-mexyl, in Wheat Forage, Hay, Grain and Straw, 050005, MRID: N/A, DACO: 7.4.1,7.4.2

1283366 2006, A Confined Rotational Crop Study with 14C-XDE-742, 040003, MRID: N/A, DACO: 7.4.3

1283069 2003, XDE-742/BAS770H - Acute Oral Toxicity Study in Rats, 031037, DACO: 4.2.1

1283071 2003, XDE-742/BAS770H - Acute Dermal Toxicity Study in Rats, 031036, DACO: 4.2.2

1470370 2007, Dow AgroSciences Response to Acute Inhalation Toxicity NAFTA Review of XDE-742 (Pyroxsulam), GF-1674 and GF-1274 (PMRA 4.2.3 / EPA 81-3 / APVMA 3-4.2), DF-09182007, DACO: 4.2.3,4.6.3

1283074 2003, XDE-742/BAS770H - Acute Eye Irritation in Rabbits, 032100, DACO: 4.2.4

1283076 2003, XDE-742/BAS770H - Acute Dermal Irritation/Corrosion in Rabbits, 032102, DACO: 4.2.5

1283078 2004, XDE-742/BAS770H - Maximization Test in Guinea Pigs, 032101, DACO: 4.2.6

1283081 2003, XDE-742/BAS-770H: 90-Day Dietary Toxicity Study in CD-1 Mice:, 021106,. DACO: 4.3.1

1283082 2003, XDE-742/BAS-770H: 90-Day Dietary Toxicity Study with a 28-Day Recovery in Fischer 344 Rats, 021107, DACO: 4.3.1

1283085 2004, XDE-742: One-Year Dietary Toxicity Study in Beagle Dogs, 031012, DACO: 4.3.2

1283086 2003, XR-742/BAS-770H: 90-Day Dietary Toxicity Study in Beagle Dogs, 021111, DACO: 4.3.2

1283087 2005, Study Profile Template (SPT) for XR-742: 28-Day Dietary Toxicity Study in Fischer 344 Rats, 011044.SPT, DACO: 4.3.3

1283088 2006, Study Profile Template (SPT) for XR-742: A Range-finding and 28 Day Dietary Toxicity Study in Dogs, 3504.175.SPT, DACO: 4.3.3

1283089 2002, XDE-742: A Range-Finding and 28-Day Dietary Toxicity Study in Dogs, 011062, DACO: 4.3.3

1283090 2001, XR-742: 28-Day Dietary Toxicity Study in Fischer 344 Rats, 011044, DACO: 4.3.3

1283091 2006, Waiver Request - 14 Day Dermal study submitted under 4.8 (03020), N/A, DACO: 4.3.5

1283093 2005, XDE-742: Two-Year Chronic Toxicity/Oncogenicity and Chronic Neurotoxicity Study in Fischer 344 Rats, 031014, DACO: 4.4.1,4.4.4

1283095 2005, XDE-742: 18-Month Dietary Oncogenicity in CD-1 Mice, 031015, DACO: 4.4.3

1283097 2005, XDE-742: Chronic Neurotoxicity Study in Fischer 344 Rats, 031014, DACO: 4.4.5

1283099 2004, XDE-742/BAS 770H: One-Generation Reproduction Toxicity Study in Wistar Rats (Range-Finding) Oral Administration (Diet), 03022, DACO: 4.5.1

1283100 2005, XDE-742: Two-Generation Dietary Reproductive Toxicity Study in CD Rats, 041012, DACO: 4.5.1

1283103 2004, XDE-742/BAS 770H: Maternal Toxicity Study in Wistar Rats (Range-Finding) Oral Administration (Gavage), 03022, DACO: 4.5.2

1283104 2005, XDE-742: Oral Gavage Developmental Toxicity Study in CRL:CD(SD) Rats, 051053, DACO: 4.5.2

1283105 2005, Oral Dose Range-Finding Prenatal Developmental Toxicity Study of XDE-742 in Rabbits, 041136, DACO: 4.5.3

1283106 2005, Oral Prenatal Developmental Toxicity Study of XDE-742 in Rabbits, 041145, DACO: 4.5.3

1283108 2003, Salmonella Typhimurium/Escherichia Coli Reverse Mutation Assay (Standard Plate Test and Preincubation Test) With XDE-742/BAS770H, 034051, DACO: 4.5.4

1283110 2004, Evaluation of XDE-742 in an In Vitro Chromosomal Aberration Assay Utilizing Rat Lymphocytes, 041005, DACO: 4.5.5

1283112 2004, Evaluation of XDE-742 in the Chinese Hamster Ovary Cell/Hypoxanthine-Phosphoribosyl Transferase (CHO/HGPRT) Forward Mutation Assay, 041003, DACO: 4.5.6

1283114 2004, Revised Report for: Evaluation of XDE-742 in the Mouse Bone Marrow Micronucleus Test, 041004, DACO: 4.5.7

1283118	2005, XDE-742: Metabolism and Pharmacokinetics of 14C-XDE-742 in Male Fischer 344 Rats Following Single and Repeated Oral Administration, 041019, DACO: 4.5.9
1283119	2006, XDE-742: Pharmacokinetics of 14C - XDE-742 in CD-1 Mice Following Single Oral Gavage Administration, 061017, DACO: 4.5.9
1283122	2004, XDE-742/BAS 770H - Dermal Test Study in Wistar Rats Application for 2 Weeks, 03020, DACO: 4.8
1369031	2006, XDE-742: Measurement of unscheduled DNA synthesis in mouse liver using an in vivo/in vitro procedure, 295/169-D6173, DACO: 4.8
1283329	2006, Acute Oral Toxicity Up and Down Procedure in Rats, 050144, DACO: 4.6.1
1283331	2006, Acute Dermal Toxicity Study in Rats - Limit Test, 050147, DACO: 4.6.2
1283334	2006, Primary Eye Irritation Study in Rabbits, 050149, DACO: 4.6.4
1283336	2006, Primary Skin Irritation Study in Rabbits, 050148, DACO: 4.6.5
1283338	2005, GF-1674: Local Lymph Node Assay in nBALB/cAnCrl Mice, 051168, DACO: 4.6.6

3.0 Environment

Numéro de document de l'ARLA	Référence
1283133	2006, Cloquintocet-mexyl: Independent Laboratory Validation of Analytical Method ETL M 312 for the Determination of Cloquintocet-mexyl and its Acid Metabolite in Soil, 050004, MRID: N/A, DACO: 8.2.2.1
1283134	2006, Method Validation Report for the Determination of Cloquintocet-mexyl and its Acid Metabolite in Soil Using Enviro-Test Laboratories Method M312l, ETL04DOW04, MRID: N/A, DACO: 8.2.2.1
1283136	2006, Method Validation Report for the Determination of Residues of XDE-742 and its Metabolites in Soil and Sediment by Liquid Chromatography with Tandem Mass Spectrometry Detection Using Dow AgroSciences Method GRM 05.05, 041024, MRID: N/A, DACO: 8.2.2.1
1283137	2006, Method Validation Report for the Determination of Residues of XDE-742 in Soil and Sediment by Liquid Chromatography with Tandem Mass Spectrometry Detection Using Dow AgroSciences Method GRM 06.01, 051038, MRID: N/A, DACO: 8.2.2.1,8.2.2.2

1283140 2006, XDE-742: Independent Laboratory Validation of Dow AgroSciences LLC Analytical Method GRM 05.05 - Determination of Residues of XDE-742 and its Metabolites in Soil and Sediment by Liquid Chromatography with Tandem Mass Spectrometry Detection Using Detection, 050003, MRID: N/A, DACO: 8.2.2.1,8.2.2.2

1283141 2006, Independent Laboratory Validation of Dow AgroSciences LLC Method GRM 05.19 - Determination of Residues of XDE-742 and its Metabolites in Drinking Water, Ground Water, and Surface Water by Liquid Chromatography with Tandem Mass Spectrometry Detection, 060006, MRID: N/A, DACO: 8.2.2.3

1283143 2006, Validation Report for Method GRM 05.19 - Determination of Residues of XDE-742 and its Metabolites in Drinking Water, Ground Water, and Surface Water by Liquid Chromatography with Tandem Mass Spectrometry, 051039, MRID: N/A, DACO: 8.2.2.3

1283144 2006, Method Validation Report for the Determination of Residues of XDE-742 in Agricultural Commodities by Liquid Chromatography with Tandem Mass Spectrometry Using Dow AgroSciences LLC Method GRM. 04-17, 041026, MRID: N/A, DACO: 7.2.1,7.2.2,8.2.2.4

1283146 2005, Independent laboratory Validation of Dow AgroSciences LLC Method GRM. 04-17 - Determination of Residues of XDE-742 in Agricultural Commodities by Liquid Chromatography with Tandem Mass Spectrometry, 040095, MRID: N/A, DACO: 7.2.3,8.2.2.4

1283147 2006, Independent Laboratory Validation of XDE-742: Assessment and Validation of the European Multi-Residue Enforcement Method(s) for the Determination of XDE-742 in Plant Material, Foodstuffs of Animal Origin, Soil and Body Fluids, 050045, MRID: N/A, DACO: 7.2.3,8.2.2.4

1283149 2005, XDE-742: Assessment and Validation of European Multi Residue Enforcement Method(s) for the Determination of XDE-742 in Plant Materials, in Foodstuffs of Animal Origin, in Soil, and in Body Fluids, 051001, MRID: N/A, DACO: 7.2.4,8.2.2.4

1283150 2005, XDE-742: Assessment and Validation of European Multi Residue Enforcement Method(s) for the Determination of XDE-742 in Plant Materials, in Foodstuffs of Animal Origin, in Soil, and in Body Fluids, 051001.SPT, MRID: N/A, DACO: 7.2.4,8.2.2.4

1283151 2004, Hydrolysis of XDE-742 at pH 5, 7, and 9, 040008, MRID: N/A, DACO: 8.2.3.2

1283153 2005, Photodegradation of XDE-742 on Soil, 040014, MRID: N/A, DACO: 8.2.3.3.1

1283155 2006, Aqueous Photolysis of XDE-742 in pH 7 Buffer Using a Xenon Lamp, 040002, MRID: N/A, DACO: 8.2.3.3.2

1283157 2006, Aerobic Soil Degradation of 14C-XDE-742 in Four European Soils, 030013, MRID: N/A, DACO: 8.2.3.4.2

1283159 2006, Aerobic Soil Degradation Rate of XDE-742 in 16 European and North American Soils, 030012, MRID: N/A, DACO: 8.2.3.4.2

1283160 2006, Aerobic Soil Metabolism of 5,7-di-OH-XDE-742, 050042, MRID: N/A, DACO: 8.2.3.4.2

1283164 2005, Anaerobic Degradation of XDE-742 on One European Soil, 030051, MRID: N/A, DACO: 8.2.3.4.4,8.2.3.5.6

1283166 2006, Aerobic Aquatic Degradation of XDE-742 in Two European Sediment and Pond Water Systems, 030076, MRID: N/A, DACO: 8.2.3.5.4

1283168 2006, Soil Batch Equilibrium Adsorption of 14C-XDE-742 Metabolites, 050019, MRID: N/A, DACO: 8.2.4.2

1283169 2004, Soil Batch Equilibrium Adsorption/Desorption of 14C-XDE-742, 030069, MRID: N/A, DACO: 8.2.4.2

1283174 2006, Freezer Storage Stability in Plant Materials (XDE-742) and in Soil (XDE-742 and Three of its Metabolites), P846G, MRID: N/A, DACO: 8.6

1430702 2004, Soil Batch Equilibrium Adsorption/Desorption of 14C - XDE-742, 030069, MRID: 36908332, DACO: 8.2.4.2

1430704 2006, Soil Batch Equilibrium Adsorption/Desorption of 14C - XDE-742, 030069.SPT, MRID: 46908533, DACO: 8.2.4.2

1450772 2007, Aerobic Degradation of XDE-742 in 4 European Soils Employing Exhaustive Extraction Methods, 060113, MRID: N/A, DACO: 8.2.4.3.2

1472458 2007, Request for Information fro XDE-742 Technical Herbicide (Pyroxsulam) Phototransformation Study in Water, N/A, MRID: N/A, DACO: 8.2.3.3.2

1508398 2006, Aqueous Photolysis of XDE-742 in pH 7 Buffer Using a Xenon Lamp, 040002, MRID: 46908327, DACO: 8.2.3.3.2

1283372 2006, Terrestrial Field Dissipation of XDE-742 Herbicide and Cloquintocet Safener in Canada, 040037, MRID: N/A, DACO: 8.3.2

1283180 2006, 5-OH Metabolite of XDE-742: An Acute Toxicity Study with the Earthworm in an Artificial Soil Substrate, 379-160, MRID: N/A, DACO: 9.2.3.1

1283181 2006, 6-C1-7-OH Metabolite of XDE-742: An Acute Toxicity Study with the Earthworm in an Artificial Soil Substrate, 379-161, MRID: N/A, DACO: 9.2.3.1

1283182 2006, 7-OH Metabolite of XDE-742: An Acute Toxicity Study with the Earthworm in an Artificial Soil Substrate, 379-159, MRID: N/A, DACO: 9.2.3.1

1283187 2005, XDE-742: 14-Day Soil Exposure Acute Tocicity to the Earthworm, Eisenia foetida, 2731-DO, MRID: N/A, DACO: 9.2.3.1

1283188 2004, Effects of XDE-742/BAS770H (Acute Contact and Oral) on Honey Bees (Apis mellifera L.) in the Laboratory, 18361035, MRID: N/A, DACO: 9.2.4.1,9.2.4.2

1283191 2006, 7-OH Metabolite of XDE-742 - Acute Toxicity to Water Fleas, Daphnia magna, Under Static Conditions, 12550-6410, MRID: N/A, DACO: 9.3.2

1283192 2006, ATSA Metabolite of XDE-742 - An Acute Toxicity Study with the Daphnid, Daphnia magna, 061005, MRID: N/A, DACO: 9.3.2

1283197 2004, XDE-742: An Acute Toxicity Study with the Daphnid, Daphnia magna, 041022, MRID: N/A, DACO: 9.3.2

1283199 2005, XDE-742: A 21-Day Chronic Toxicity Study with the Daphnid, Daphnia magna, 041023, MRID: N/A, DACO: 9.3.3

1283200 2006, 7-OH Metabolite of XDE-742 - Chironomid Toxicity Test with Midge (Chironomus riparius) Under Static Conditions Using Spiked Water, 12550.6412, MRID: N/A, DACO: 9.3.4

1283204 2005, XDE-742: 28-Day Chronic Toxicity Study with the Midge, Chironomus riparius, Using Spiked Water in a Sediment-Water Exposure System, 041061, MRID: N/A, DACO: 9.3.4

1283206 2006, 7-OH Metabolite of XDE-742 - Acute Toxicity to Rainbow Trout (Oncorhynchus mykiss) Under Static Conditions, 12550.6411, MRID: N/A, DACO: 9.5.2.1

1283207 2003, Acute Toxicity Study on the Rainbow Trout (Oncorhynchus mykiss) in a Static System over 96 hours, 035031, MRID: N/A, DACO: 9.5.2.1

1283208 2006, ATSA Metabolite of XDE-742 - An Acute Toxicity Study with the Rainbow Trout, Oncorhynchus mykiss, 061010, MRID: N/A, DACO: 9.5.2.1

1283212 2003, Acute Toxicity Study on the Fathead Minnow (Pimephales promelas) in a Static System over 96 Hours, 035032, MRID: N/A, DACO: 9.5.2.2,9.5.2.3

1283215 2005, XDE-742: Toxicity to the Early-Life Stages of the Fathead Minnow, Pimephales promelas, 051007, MRID: N/A, DACO: 9.5.3.1

1283218 2003, XDE-742 / BAS 770 H - Avian Single-Dose Oral LD50 on the Bobwhite Quail (Colinus virginianus), 035027, MRID: N/A, DACO: 9.6.2.1

1283220 2003, XDE-742 / BAS 770 H - Avian Single-Dose Oral LD50 on the Mallard Duck (Anas platyrhynchos), 035028, MRID: N/A, DACO: 9.6.2.2

1283222 2005, XDE-742 - Dietary Toxicity Test with the Northern Bobwhite Quail (Colinus virginianus), 12550.4111, MRID: N/A, DACO: 9.6.2.4

1283224 2004, XDE-742: Dietary Toxicity Test with the Mallard Duck (Anas platyrhynchos), 12550.4114, MRID: N/A, DACO: 9.6.2.5

1283226 2005, XDE-742: Reproductive Toxicity Test with the Northern Bobwhite Quail (Colinus virginianus), 12550.4113, MRID: N/A, DACO: 9.6.3.1

1283228 2005, XDE-742: Reproductive Toxicity Test with the Mallard Duck (Anas platyrhynchos), 12550.4116, MRID: N/A, DACO: 9.6.3.2

1283230 2006, 5,7-Di-OH Metabolite of XDE-742 - Acute Toxicity to the Freshwater Green Alga, Pseudokirchneriella subcapitata, 12550.6417, MRID: N/A, DACO: 9.8.2

1283231 2006, 5-OH Metabolite of XDE-742 - Acute Toxicity to the Freshwater Green Alga, Pseudokirchneriella subcapitata, 12550.6405, MRID: N/A, DACO: 9.8.2

1283232 2006, 6-Cl-7-OH Metabolite of XDE-742 - Acute Toxicity to the Freshwater Green Alga, Pseudokirchneriella subcapitata, 12550.6402, MRID: N/A, DACO: 9.8.2

1283233 2005, 7-OH Metabolite of XDE-742 - Acute Toxicity to the Freshwater Green Alga, Pseudokirchneriella subcapitata, 12550.6408, MRID: N/A, DACO: 9.8.2

1283234 2006, ADTP Metabolite of XDE-742 - Acute Toxicity to the Freshwater Green Alga, Pseudokirchneriella subcapitata, 12550.6414, MRID: N/A, DACO: 9.8.2

1283235 2006, ATSA Metabolite of XDE-742 - Growth Inhibition Test with the Freshwater Green Alga, Pseudokirchneriella subcapitata, 061002, MRID: N/A, DACO: 9.8.2

1283246 2005, XDE-742 Sulfinic Acid Metabolite - Acute Toxicity to the Freshwater Green Alga, Pseudokirchneriella subcapitata, 12550.6398, MRID: N/A, DACO: 9.8.2

1283247 2005, XDE-742: Growth Inhibition Test with the Freshwater Blue-Green Alga (Anabaena flos-aquae), 12550.6366, MRID: N/A, DACO: 9.8.2

1283248 2005, XDE-742: Growth Inhibition Test with the Freshwater Diatom, Navicula pelliculosa, 12550.6267, MRID: N/A, DACO: 9.8.2

1283249 2004, XDE-742: Growth Inhibition Test with the Freshwater Green Alga, Pseudokirchneriella subcapitata, 041054, MRID: N/A, DACO: 9.8.2

1283251 2005, XDE-742: Growth Inhibition Test with the Saltwater Diatom, Skeletonema costatum, 051039, MRID: N/A, DACO: 9.8.3

1283252 2006, Effects of GF-1674 on Seedling Emergence and Seedling Growth on Non-Target Terrestrial Plants (Tier II) - 2005, ACE-05-213, MRID: N/A, DACO: 9.8.4

1283253 2006, Effects of GF-1674 the Vegetative Vigour of Non-Target Terrestrial Plants (Tier II) - 2005, ACE-05-214, MRID: N/A, DACO: 9.8.4

1283254 2006, Herbicidal Activity of XDE-742 Soil Metabolites on Weeds and Crops in a Discovery Weed Management Level 3 Postemergence Screen, GH-C 5829, MRID: N/A, DACO: 9.8.4

1283255 2006, Herbicidal Activity of XDE-742 Soil Metabolites on Weeds and Crops in a Discovery Weed Management Level 3 Postemergence Screen, GH-C 5829.SPT, MRID: N/A, DACO: 9.8.4

1283257 2006, 5,7-Di--OH Metabolite of XDE-742 - Toxicity to Duckweed, Lemna gibba, 12550.6418, MRID: N/A, DACO: 9.8.5

1283258 2006, 5-OH Metabolite of XDE-742 - Toxicity to Duckweed, Lemna gibba, 12550.6406, MRID: N/A, DACO: 9.8.5

1283259 2006, 6-C1-7-OH Metabolite of XDE-742 - Toxicity to Duckweed, Lemna gibba, 12550.6403, MRID: N/A, DACO: 9.8.5

1283260 2006, 7-OH Metabolite of XDE-742 - Toxicity to Duckweed, Lemna gibba, 12550.6409, MRID: N/A, DACO: 9.8.5

1283261 2006, ADTP Metabolite of XDE-742 - Toxicity to Duckweed, Lemna gibba, 12550.6415, MRID: N/A, DACO: 9.8.5

1283262 2006, ATSA Metabolite of XDE-742 - Growth Inhibition Test with the Aquatic Plant Duckweed, Lemna gibba, 061006, MRID: N/A, DACO: 9.8.5

1283263 2005, Inhibition of Growth of the Aquatic Plant Duckweed, Lemma gibba, Following One and Three Day Exposures to XDE-742, 051169, MRID: N/A, DACO: 9.8.5

1283273 2005, XDE-742 Sulfinic Acid Metabolite - Toxicity to Duckweed, Lemna gibba, 12550.6399, MRID: N/A, DACO: 9.8.5

1283274 2005, XDE-742: Growth Inhibition Test with the Aquatic Plant Duckweed, Lemna gibba, 041124, MRID: N/A, DACO: 9.8.5

1283275 2006, 6-CI-7-OH Metabolite of XDE-742: A Reproduction Study with the Earthworm in an Artificial Soil Substrate, 379-162, MRID: N/A, DACO: 9.9

1283276 2006, Spray Drift Assessment of XDE-742 for Terrestrial and Aquatic Non-Target Organisms in Canada, 061028, MRID: N/A, DACO: 9.9

1508399 2007, XDE-742: 28-Day Chronic Toxicity Study with the Midge, Chironomus riparius, Using Spiked Water in a Sediment-Water Exposure System, 041061, DACO: 9.3.4

4.0 Value

1283296 2006, GF-1674 Herbicide Efficacy Trials, N/A, MRID: N/A, DACO: 10.2.3.3

1283297 2006, GF-1674 Tank Mix Efficacy Trials, N/A, MRID: N/A, DACO: 10.2.3.3

1283308 2006, GF-1674 Herbicide Non-Safety Adverse Effects, N/A, MRID: N/A, DACO: 10.3.2

1303451 Field Trial Reports 2001-2005. Use of DE-742 for Postemergence Control of Wild Oats, Hemp nettle, Cleavers, Common Chickweed, Redroot Pigweed,Smartweed/Ladys thumb and Volunteer Canola in Spring and Durum Wheat in the Prairie Provinces and Peace River of

Published Information

1327295 Government of Saskatchewan, 1999. The Noxious Weeds Designation Regulations. www.canlii.org/sk/laws/regu/n-9.1r.2/20060927/whole.html

1327303 Alberta Government, 2004. Agriculture, Food and Rural Development. Restricted, Noxious, and Nuisance Weeds in Alberta: Frequently Asked Questions. www1.agric.gov.ab.ca/$department/deptdocs.nsf/all/faq8261

1327308 Government of Manitoba, 2006. Pest Management - Weeds - Declaration of Noxious Weeds in Manitoba -Manitoba Agriculture, Food and Rural Initiatives. www.gov.mb.ca/agriculture/crops/weeds/fab64s00.html